EXHIBIT 1

LEXSEE 1997 U.S. DIST. LEXIS 23954

ZENITH LABORATORIES, INC., Plaintiff, v. ABBOTT LABORATORIES, Defendants.

Civil Action No. 96-1661

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

1997 U.S. Dist. LEXIS 23954

October 1, 1997, Decided
October 2, 1997, Filed; October 3, 1997, Entered on the Docket

NOTICE: [*1] NOT FOR PUBLICATION

DISPOSITION: Zenith's motion for a preliminary injunction denied.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff drug manufacturer sued defendant drug company for (1) unfair competition; (2) abuse of process; (3) tortious interference; and (4) fraud. Plaintiff sought a declaratory judgment that plaintiff was not infringing defendant's patents and a preliminary injunction to enjoin defendant from continuing to list two United States Patents in the Food and Drug Administration's (FDA) "Orange Book."

OVERVIEW: Plaintiff wanted to market a generic version of one of defendant's patented drugs, which was approved by the FDA. Plaintiff sought to enjoin defendant's listings in the FDA's "Orange Book," as illegal and because they irreparably injured plaintiff's efforts to offer the generic version. The court noted that the party seeking to alter the status quo had a particularly heavy burden of proof, and that *21 U.S.C.S. § 355*(c)(2) was the governing statute. The court ruled that plaintiff failed to show that it had a likelihood of success on the merits or that it would suffer irreparable harm. The FDA's approval of the listing of defendant's patents cast doubt on plaintiff 's likelihood of success on the merits. Moreover, plaintiff failed to make a sufficient showing of irreparable harm because an allegation that it would suffer if other competitors got on the market before plaintiff did was largely economic in nature; economic loss was an insufficient basis on which to premise an award of injunctive relief. The court had no need to consider the factors of public interest or review a balance of hardships.

OUTCOME: Plaintiff's motion for a preliminary injunction was denied.

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JUDGES: JOHN W. BISSELL, United States District Judge.

OPINIONBY: JOHN W. BISSELL

OPINION: BISSELL, District Judge

This matter comes before the Court on a motion for a preliminary injunction by Plaintiff Zenith Laboratories, Inc. ("Zenith") to enjoin Defendant Abbott Laboratories ("Abbott") from continuing to list two United States Patents in the Food and Drug Administration's ("FDA") "Orange Book." Zenith instituted this action against Abbott on April 15, 1996. The Complaint charges Abbott with unfair [*2] competition, abuse of process, tortious

interference and fraud. It also seeks a declaratory judgment that Zenith is not infringing Abbott's relevant patents

Abbott previously moved before this Court to dismiss the Complaint pursuant to *Fed. R. Civ. P. 12(b)(6)*, and Zenith cross-moved for partial summary judgment on the issue of whether the listing of four of Abbott's patents (including the two at issue in the present motion) in the Orange Book was improper. On August 5, 1996, this Court issued and Opinion and Order denying both motions.

The Court has subject matter jurisdiction pursuant to *28 U.S.C. § 1331*.

I. STATUTORY FRAMEWORK

An intricate statutory system governs the subject matter of this lawsuit. The FDA has the authority to regulate the manufacture, distribution, and sale of drugs within the United States pursuant to the Federal Food and Drug Cosmetic Act ("FFDCA"). *21 U.S.C. § 355*(a). Pharmaceutical companies seeking approval to market a new drug (or a "pioneer drug") must first file a new drug application ("NDA") with the FDA. In order for an application to be successful, it must set forth in detail the numerous [*3] tests conducted by the pharmaceutical company which show the safety and effectiveness of the drug it seeks to market. *21 U.S.C. § 355*(d). Only after the FDA approves an NDA can the pharmaceutical company market its drug product in the United States. *21 U.S.C. § 355*(a).

The FDA is required to publish a list of the "official and proprietary name" of each drug it approves (along with certain other information provided by the pioneer drug manufacturer), which it does in a publication called Approved Drug Products Therapeutic Equivalence Evaluations (also known as the "Orange Book"). See *21 U.S.C. § 355*(j)(6). Information related to Abbott's NDA for Hytrin and Abbott's patents covering its various forms of terazosin hydrochloride are listed in the Orange Book. (See Coleman Decl., P 2). Once a drug has been approved and listed, another drug manufacturer may seek FDA marketing approval for an identical or closely related product (or "generic" drug) by submitting and having approved an abbreviated new drug application ("ANDA"). The FDA will approve the generic drug when the applicant can demonstrate that generic [*4] drug is as safe and effective as the pioneer drug.

In 1984, the FFDCA was amended to include the Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417, 98 Stat. 1585 (1984) (codified as amended at *21 U.S.C. § 355* (1994) and *35 U.S.C. § 271*(d)-(h) (1995)). This Act is more commonly referred to as the "Hatch-Waxman Amendments" to the FFDCA. These Amendments significantly relaxed the procedures for approval of ANDA's. The Hatch-Waxman Amendments permit a generic drug manufacturer to rely on the safety and effectiveness data compiled and submitted by the pioneer drug manufacturer in connection with its NDA. See *21 U.S.C. § 355*(j). The generic drug manufacturer need only show that its drug contains the same active ingredient as, and that it is bioequivalent to, the patented drug.

An ANDA applicant seeking to rely on the safety and effectiveness data previously submitted in connection with a listed drug must file:

> a certification . . . with respect to each patent which claims the listed drug . . .
>
> I. that the pioneer has not filed patent information with the FDA,
>
> II. that the patent [*5] has expired,
>
> III. that the patent expires on a date before which the generic manufacturer is seeking to market its infringing equivalent, or
>
> IV. that the patent claiming the marketed pioneer drug is invalid or will not be infringed

21 U.S.C. § 355(j)(2)(vii). An ANDA applicant who makes a Paragraph IV certification must notify the patent holder of its intention and, under the Hatch-Waxman Amendments, the patent holder is given a window of opportunity to litigate any patent disputes before the certifying generic company is permitted to put its drug on the market. The patent holder has 45 days from the date of receiving notice of the ANDA applicant's certification to bring a patent infringement suit, and the filing of such suit precludes FDA approval of the ANDA for up to 30 months, pending the resolution of the patent infringement claims in the courts. See *21 U.S.C. § 355*(j)(4)(B)(iii); *21 C.F.R. § 314.107(b)(3)(B)(ii)* and (e).

II. STATEMENT OF THE CASE n1

n1 A more detailed history of the dispute between Zenith and Abbott is set forth in the Court's August 1996 Opinion. (See 8/5/96 Op. at 2-8).

[*6]

Zenith seeks to market a generic version of Abbott's terazosin hydrochloride drug, Hytrin. Abbott discovered the drug substance terazosin hydrochloride, which is used to treat hypertension and benign prostatic hyperplasia. Currently, terazosin hydrochloride has been found to exist in both dihydrate (containing water) and anhydrous (containing no water) forms. Abbott's Hytrin, as approved for sale and use by the FDA in 1987, contained the dihydrate form of terazosin hydrochloride.

Abbott was awarded the following patents related to terazosin hydrochloride:

U.S. Patent No.	Covering
4,026,894 ("'894 patent")	terazosin hydrochloride itself (in any form)
4,112,097 ("'097 patent")	a particular pharmaceutical composition of terazosin hydrochloride, as well as a method of treatment
4,251,532 ("'532 patent")	Hytrin (containing the dihydrate form of terazosin hydrochloride)
5,294,615 ("'615 patent")	Form II, one of the three anhydrous crystalline polymorphs of terazosin hydrochloride.
5,412,095 ("'095 patent")	Form III, another anhydrous crystalline polymorph of terazosin hydrochloride.
5,504,207 ("'207 patent")	Form IV, the third anhydrous crystalline polymorph of terazosin hydrochloride.

[*7]

It is Abbott's '095 and '207 patents that are the subject of Zenith's present motion for a preliminary injunction. n2 These patents do not expire until 2013 and 2014, respectively. Zenith seeks to preliminarily enjoin Abbott from continuing to list its '095 and '207 patents in the Orange Book on the grounds that such listings are illegal and that they are irreparably injuring Zenith's efforts to offer a generic version of Hytrin. The essence of Zenith's claim against Abbott is that neither the '095 patent nor the '207 patent "claim" Hytrin and, thus, that these two patents are ineligible for listing in the Orange Book. Abbott contends that the instant lawsuit represents Zenith's attempt to bypass the intricate statutory system for the resolution of patent infringement claims during the FDA approval process.

n2 The '894 patent expired in 1994, and the '097 patent expired in 1995. See *Abbott Lab. v. Novopharm Ltd., 1996 U.S. Dist. LEXIS 3139, 38 U.S.P.Q.2D (BNA) 1309 (N.D. Ill. 1996)*, aff'd *104 F.3d 1305 (Fed. Cir. 1997)*. The '615 patent is not in dispute, because Zenith has been advised by the FDA that it is not required to file a certification with respect to this patent on account of the timing of its inclusion in the Orange Book. (See Zenith's Br. at 12 n.18). The '532 patent expires later this year, but Abbott has never contested the reasons that Zenith has given as to why its generic drug does not infringe the '532 patent. (See Rocco Decl., P 7).

[*8]

Last year, shortly after the Complaint in this action was filed, Abbott filed a motion to dismiss the Complaint and Zenith filed a motion for summary judgment on the ground that the listing of, inter alia, the '095 and '207 patents was improper and for a permanent injunction, seeking the entry of an order directing Abbott to delist those patents. On August 5, 1996, the Court denied both Abbott's and Zenith's motions. The Court did not decide the issue of whether Abbott's patents for the anhydrous polymorphs of terazosin hydrochloride (which describes both the '095 and '207 patents) were properly listed in the Orange Book, because the Court found that the following issue of material fact remained in dispute:

> The contested patents are for different anhydrous polymorphs of terazosin hydrochloride. As stated above, different polymorphic forms containing the same active ingredient may be considered by the FDA as equivalents. However, this is the case only if the dissolution, solubility and absorption of the polymorphs are the same. It is not clear that these factors are consistent as between Hytrin and the later patents.

(See 8/5/96 Op. at 24). Since the Court's [*9] decision last year, the FDA answered the Court's question in the affirmative. Specifically, the FDA determined that the anhydrous versions and the dihydrate version of terazosin hydrochloride are properly considered pharmaceutically equivalent or bioequivalent. (See Abbott's Opp. Br., Exhs. 2, 3). Although Zenith concedes this point, as it must, it nevertheless contends that this question is "legally unrelated" to whether Abbott's listings are proper. (See Zenith's Br. at 27).

Zenith has not received tentative approval from the FDA to market its generic version of the drug substance terazosin hydrochloride. In March 1996, Zenith was advised by the FDA that it would not approve Zenith's ANDA absent a certification as to Abbott's '095 and '207 patents. (See First Rocco Decl., PP 13-14). In July 1997, Zenith received word from the FDA that, because it had not provided certifications as to all of Abbott's patents listed in the Orange Book, the file for Zenith's ANDA is now closed. (See Second Rocco Decl., Exh. B).

At the present time, two other drug companies seeking to market a generic version of Hytrin are actively engaged in patent litigation with Abbott in the Northern [*10] District of Illinois (summary judgment motions in both cases are pending). n3 These companies, Geneva Pharmaceuticals and Novopharm Limited, filed the certifications under the Hatch-Waxman Amendments (relating to the '207 patent, in particular) that Zenith refuses to file. Geneva and Novopharm have received tentative approval, pending the resolution of the patent infringement suit, from the FDA to market their generic drugs. (See Abbott's Opp. Br., Exhs. 4, 5).

n3 A third company, Mylan Pharmaceuticals, recently voiced its intention to market a generic version of Hytrin, and patent litigation between itself and Abbott has commenced.

III. ANALYSIS

A. Standard for Preliminary Injunction

The Third Circuit standard governing a preliminary injunction is as follows:

> In considering a motion for preliminary injunctive relief, a court must carefully weigh four factors: (1) whether the movant has shown a reasonable probability of success on the merits; (2) whether the movant will be irreparably [*11] injured by denial of such relief; (3) whether granting preliminary relief will result in even greater harm to the nonmoving party; and (4) whether granting preliminary relief will be in the public interest.

SI Handling Systems, Inc. v. Heisley, 753 F.2d 1244, 1254 (3d Cir. 1985); see also *Hoxworth v. Blinder, Robinson & Co., Inc., 903 F.2d 186, 197-198 (3d Cir. 1990), Klitzman, Klitzman and Gallagher v. Krut, 744 F.2d 955, 958-959 (3d Cir. 1984), Continental Group v. Amoco Chemicals Corp., 614 F.2d 351, 356-57 (3d Cir. 1980)*. Preserving the status quo of an action pending final determination is the primary purpose of a preliminary injunction. *In re Arthur Treacher's Franchise Litigation, 689 F.2d 1150 (3d Cir. 1982)*. A plaintiff's failure to establish both items (1) and (2) above will necessarily result in the denial of the preliminary injunction. *Morton v. Beyer, 822 F.2d 364, 367 (3d Cir. 1987)*, In re Arthur Treacher's Franchisee *Litigation, 689 F.2d 1137, 1143 (3d Cir. 1982)*.

B. Likelihood That Zenith Will Succeed on the Merits

First, it is important [*12] to remember that the primary purpose of a preliminary injunction is to pre-

serve the status quo of an action pending final determination and that, in the present case, an award of injunctive relief would run contrary to this purpose -- i.e., it would disrupt the status quo by removing two patents from the Orange Book. As Zenith is the party seeking to alter the status quo, it bears a particularly heavy burden in demonstrating that an award of injunctive relief in its favor is warranted. See *Acierno v. New Castle County, 40 F.3d 645, 653 (3d Cir. 1994)*. For the reasons set forth below, the Court determines that Zenith has not sustained its burden.

Both sides agree that the merits of Zenith's claims in this case turn on the question of whether the '095 and '207 patents should be listed in the Orange Book. Thus, the Court's analysis begins with the listing requirements for new drugs, such as Hytrin, as defined in *21 U.S.C. § 355*

> The holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a **[*13]** method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(c)(2). Though both sides agree that this is the governing statute, the proper reading of it is disputed.

Abbott contends that the statute entitles the holder of an NDA to list: (1) with respect to drug patents, the patent number and expiration date of any patent which claims the drug for which the NDA was submitted, or (2) with respect to method-of-use patents, the patent number and expiration date of any patent which claims a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug for which the NDA was filed. Applying this interpretation to the present case: because the '095 and '207 patents are drug patents (no one argues that they are method patents), Abbott would be entitled to list the '095 and '207 patents in the Orange Book if they claim the drug Hytrin.

Zenith reads the statute differently. **[*14]** Pursuant to its interpretation, the last clause, "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." applies not only to the listing of patents which claim a method of using a drug but, as well, to patents which claim a drug. Thus, with respect to the question of whether Abbott has properly listed the '095 and '207 patents in the Orange Book, Zenith argues that Abbott must be able to show that (1) the '095 and '207 patents claim the drug Hytrin, and that (2) Abbott could reasonably assert a claim for infringement of the '095 and '207 patents against any unlicensed person who manufactures, uses or sells Hytrin.

Reading the statute in the light most favorable to Zenith, as the moving party here, the first question that the Court must ask is whether the '095 and '207 patents "claim the drug" for which the NDA was filed. n4 In other words, can it be said that the '095 and '207 patents claim Hytrin. Zenith argues that Abbott's Hytrin is terazosin hydrochloride in its dihydrate form only. It is therefore Zenith's position that forms of terazosin hydrochloride that **[*15]** are not the dihydrate -- e.g., Form III or Form IV, those anhydrous crystalline polymorphs present in the '095 and '207 patents -- cannot "claim" Hytrin and thus should not be listed in the Orange Book.

> n4 As the following discussion will make clear, the Court need not decide the question of whose interpretation of the statute -- Zenith's or Abbott's -- is the correct one in order to dispose of the instant motion, because even assuming, arguendo, that Zenith's interpretation is correct, it still cannot demonstrate a likelihood of success on the merits of its arguments. However, the Court notes that, based on the information presented to it and the arguments of the parties, Abbott's interpretation appears to make more sense. Additionally, Abbott's position is better supported by the FDA's implementing regulations governing those patents for which Abbott must submit information to the FDA for inclusion in the Orange Book. See *21 C.F.R. § 314.53(b)*
>
> The very nature and purpose of the Orange Book makes it seem likely that the listing requirements for drug patents would be different than those for method patents, because there is no need to list in the Orange Book those method patents which do not relate to the use of the drug that is the subject of the NDA. To borrow from Abbott's own example, suppose that Abbott discovered that terazosin hydrochloride was an effective paint thinner and, thus, it obtained patent '123 for the use of that drug substance as a paint thinner. Clearly, Abbott's patent '123 would not belong in the Orange Book, because Abbott could not rea-

sonably assert that the unlicensed manufacture, use, or sale of Hytrin as a drug to treat hypertension infringed its patent on the paint thinner.

[*16]

Abbott, on the other hand, contends that although the different polymorphs of terazosin hydrochloride represent different structural arrangements of that compound, they are all essentially the same thing, namely the drug substance terazosin hydrochloride. Further, Abbott contends that, as the FDA considers the term "drug" to mean "drug substance," Hytrin, the drug, is necessarily the same thing as terazosin hydrochloride, the drug substance. It is therefore Abbott's position that any arrangement -- e.g., Forms II, III or IV -- of terazosin hydrochloride necessarily "claims" Hytrin and thus that the '095 and '207 patents are properly listed in the Orange Book.

As this Court previously recognized, the FDA considers drugs to be the same if they differ only in water of hydration. (See the Court's 8/5/96 Op. at 23 (citing Orange Book at xii, Coleman Decl., Exh. B)). The Court also recognized that, according to the FDA, "as a general matter, 'different polymorphic forms of the same drug substance [are the same] drug substances unless the differences in physical structure found in the polymorphs result in inequivalent safety and efficacy profiles,'" (id. at 24 (quoting [*17] FDA Response to Citizen Petition of Janssen Pharmaceuticals, Coleman Decl., Exh. C at 4)), and that "the FDA also considers 'differences in waters of hydration resulting in polymorphic crystal forms of the same active moiety (i.e., different forms of the same active ingredient) to be the same when dissolution, solubility, and absorption are shown to be equivalent.'" (Id., quoting Letter from the Center for Drug Evaluation and Research, Coleman Decl., Exh. D).

It was with this backdrop that the Court went on to determine that, because at the time of its 8/5/96 Opinion and Order, it was not clear that the dissolution, solubility and absorption of the anhydrous polymorphs were equivalent to Hytrin, a question of fact remained as to whether the anhydrous polymorphs -- i.e., those of the '095 and '207 patents -- were covered by the dihydrate version of terazosin hydrochloride -- i.e., Hytrin. The Court expressly stated that, "in the event these polymorphs do have the same dissolution, solubility and absorption as that found within the drug substance in Hytrin, their patents would likely be construed as properly claiming the drug substance in Hytrin ...." As the FDA has [*18] determined these factors to be equivalent as between the anhydrous polymorphs of terazosin hydrochloride and Hytrin, the Court is inclined to agree with Abbott that the '095 and '207 patents claim Hytrin. n5

n5 See also Reed Decl., PP 2, 3 (attached to Abbott's Opp. Br. at Exh. 5), and Coleman Decl., P 2 (attached to Abbott's Opp. Br. at Exh. 1).

Even if the FDA's determination does not dispose of the issue, at the very least it certainly casts considerable doubt on Zenith's likelihood of success on the merits of its claims and, thus, this now-resolved question of fact can hardly be called "legally irrelevant." This seems especially true in light of the fact that Zenith itself relied on the above-quoted statement from the Letter from the Center for Drug Evaluation and Research in its successful attempt to persuade the FDA that anhydrous and hydrated terazosin hydrochloride are the same. (See 1/22/93 Letter re: Zenith's ANDA Submission, attached as Exh. 2 to Abbott's Opp. Br.). Thus, the following inconsistency [*19] develops: When it wants to reap the benefits of (or "piggy back onto") Abbott's Hytrin testing, Zenith argues that the anhydrous and hydrated versions of terazosin hydrochloride are the same; but when it wants to take a short-cut around the very same statute that enables it to reap these benefits, Zenith argues that the versions are different. In other words, Zenith appears to be arguing out of both sides of its mouth.

Zenith places a great deal of emphasis on *Pfizer, Inc. v. Food and Drug Administration, 753 F. Supp. 171 (D. Md. 1990)*, as it did in support of its summary judgment motion last year. In Pfizer, the FDA refused to list a patent that failed to claim an approved drug product. Pfizer already had an approved patent which claimed nifedipine solution in an oral release capsule, but it sought to have approved a patent on a tablet formulation of nifedipine. Because the tablet patent did not claim the FDA-approved oral release capsule, the FDA refused to approve the listing of that patent. Pfizer brought suit against the FDA to compel the listing of that patent (# '986). The court agreed with the FDA's position that "a patent for a formulation that has never [*20] been approved may not be listed by FDA." *Id. at 174*. Thus, the court determined that a patent covering an active ingredient of an approved drug product, when placed in an unapproved formulation, was not listable in the Orange Book. Id.

Pfizer is distinguishable from the case at bar. As the Court noted in its previous Opinion, in the instant case, the patents at issue (the '905 and '207 patents) do not claim (or purport to claim) an unapproved drug product. Rather, they claim the FDA-approved drug product, Hytrin. There is no question of unapproved formulations in the instant case -- only a question of different polymorphic forms, which the FDA has recognized as equivalents of Abbott's approved drug Hytrin. Furthermore, if the anhydrous and hydrated versions of terazosin hydrochloride were as different as Zenith wants to be able to

say they are, then Zenith should also be foreclosed from asserting that the testing that was done for the NDA (for the dihydrate version) suffices for the approval of its ANDA (for the anhydrous version). That was the issue before the Pfizer court, which is not the same issue as the one facing the Court here. n6

> n6 The Court notes also that in the case at bar the FDA has approved the listing of the '095 and '207 patents at issue here. This is a recognition by the very agency charged with oversight in this area that the present case differs from Pfizer.

[*21]

The Court's analysis of the merits does not, however, end there. Assuming that Zenith is correct in its interpretation of the statute governing the listing of patents in the Orange Book, then the next question that the Court must answer is whether Abbott could reasonably assert a claim for infringement of the '095 and '207 patents against any unlicensed person's manufacture, use, or sale of Hytrin. Here, too, the FDA's broad interpretation of the drug Hytrin as terazosin hydrochloride in any form and its determination that the different polymorphs of terazosin hydrochloride are pharmaceutically equivalent make it very likely that Abbott could claim that the unlicensed manufacture, use, or sale of Hytrin would infringe its '095 and '207 patents.

It is important to remember that, even under Zenith's interpretation, the relevant language in § 355 in no way requires Abbott to be able to successfully assert a claim of patent infringement, but only that it be able to reasonably assert such a claim. Of course, as the Court here does not have before it this patent infringement claim, it need not determine the would-be fate of such a claim; rather, even under Zenith's more stringent [*22] reading of the statute, the Court need only be able to say that such a claim by Abbott would be reasonable. Based on all of the information before it and in light of the foregoing discussion regarding the FDA's position on terazosin hydrochloride, the Court determines at this juncture that Abbott could reasonably assert such a patent infringement claim.

Taking a step back from the intricacies of the language of § 355, it seems that Zenith recognizes the same to be true, given that the Amended Complaint in this case contains a declaratory judgment claim, wherein Zenith is seeking a declaration that its generic version of Hytrin drug does not infringe any of Abbott's various terazosin hydrochloride patents. (See Am. Compl., Fifth Claim PP 79-81). One could reasonably infer that Zenith seeks such a declaration because it fears that if it did market its generic version of Hytrin, Abbott would file a claim against it for alleged infringement of, inter alia, its '095 and '207 patents. In determining that Zenith had adequately pled a claim for declaratory judgment, the Court found Zenith to have a reasonable apprehension of suit and to have made meaningful preparation to commit [*23] acts that Abbott would likely contest as infringing of its patents, including its '095 and '207 patents. (See the Court's 8/5/96 Op. at 16). Logic seems to dictate that what makes Zenith's fear of suit reasonable is that Abbott could reasonably assert claims for patent infringement against it.

For the reasons discussed thus far in this Opinion, the Court determines that Zenith has not sustained its burden of establishing a likelihood of success on the merits of its claims and, thus, its motion for a preliminary injunction must fail.

C. Irreparable Harm

Even if Zenith had been able to establish a likelihood of success on the merits of its claims, Zenith's motion would nevertheless fail for the reason that Zenith has not made a sufficient showing of irreparable harm. First, contrary to Zenith's contentions, it is not entitled to a presumption of irreparable harm. The Federal Circuit will presume irreparable harm in patent infringement cases but only where the patent holder has made a clear showing of both validity and infringement. *Polymer Tech., Inc. v. Bridwell, 103 F.3d 970, 973 (Fed. Cir. 1996), 35 U.S.C. § 283*; see also *H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 390 (Fed. Cir. 1987)*, [*24] abrogated on other grounds by *Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995)*. Notwithstanding that it is Third Circuit and not Federal Circuit preliminary injunction standards that apply here, n7 Zenith is not entitled to the benefit of this presumption because, in the instant case, Zenith is not the patent holder. Furthermore, alleged patent infringement is not the basis of the preliminary injunctive relief sought here.

> n7 See, e.g., *Chemlawn Services Corp. v. GNC Pumps, Inc., 823 F.2d 515, 517 (Fed. Cir. 1987)*(deferring to Fifth Circuit law regarding preliminary injunctions because in cases where the preliminary injunction sought is not based on patent law, the trial court must apply the law of the circuit in which it sits)

Additionally, the policy considerations underlying the Federal Circuit's presumption of harm rule do not apply to Zenith. The presumption takes into consideration the fact that a patent is granted for only a finite term, which expiration [*25] date is not stayed during the

course of patent litigation. See *H.H. Robertson, 820 F.2d at 390*. The presumption also recognizes that, because "the principal value of a patent is its statutory right to exclude," monetary damages may not suffice to make the patent holder whole. Id. In an effort to persuade the Court that the presumption should nevertheless apply to it, Zenith argues that (1) the presumption is available in trademark cases, where the rights -- unlike those associated with patents -- may be perpetual, and (2) as to monetary damages not always sufficing, Zenith will not enjoy the sort of statutorily recoverable damages available to patent holders who are ultimately successful in infringement cases. (See Zenith's Reply Br. at 10 n.11).

These arguments run afoul of the rationale underlying the presumption of harm rule and, moreover, they are not persuasive. The Court fails to see the value of Zenith's first argument, as this is not a trademark infringement case and, to state it bluntly, its second argument makes no logical sense. In essence, Zenith is arguing that because it is not the patent holder here, it should be afforded greater protection **[*26]** than would be afforded a patent holder and that, somehow, this is a reasonable extrapolation of a rule meant to protect patent holders.

The other arguments that Zenith has advanced in support of its claim that it is being irreparably harmed also fall far short of warranting the extraordinary remedy Zenith is seeking here. Zenith makes much ado about the harm it will suffer if "other competitors get on the market before Zenith," fearing that "Zenith's market share will be dramatically reduced and perhaps disappear entirely." (See Zenith's Reply Br. at 9). Assuming, arguendo, that Zenith is correct in its belief that but for Abbott's Orange Book listings, it would be the first competitor in the generic marketplace, the type of harm Zenith predicts is largely economic in nature. Economic loss is an insufficient basis on which to premise an award of injunctive relief. See *Acierno, 40 F.3d at 653; In re Arthur Treacher's, 689 F.2d at 1145*. That there may exist "massive uncertainty surrounding Zenith's economic harm" (see Zenith's Reply Br. at 9), of course, does not transform the loss to harm that is irreparable and deserving of preliminary **[*27]** injunctive relief. *Mova Pharmaceutical Corp. v. Shalala, 955 F. Supp. 128 (D.D.C. 1997)*, does not persuade this Court that Zenith is threatened with irreparable injury. Mova involved a dispute as to which of two generic manufacturers should be allowed to be the first-to-market. It is thus distinguishable from the present controversy between a generic and a pioneer. Secondly, the Mova court found that the plaintiff there had demonstrated a "very high" probability of success on the merits; therefore, "a much smaller quantum of injury will sustain an application for preliminary injunction." *Id. at 131*. The Court has some doubt that this application of the preliminary injunction standards is consistent with Third Circuit law; nevertheless, Zenith has not demonstrated a probability (let alone a "very high" probability) of success on the merits of its argument to delist the '095 and '207 patents. Finally, Mova did not focus on the fact that even there, the plaintiff's alleged injury was economic and could probably be quantified.

In a way, Zenith has created the very harm it claims to be suffering. As stated numerous times in this Opinion, the **[*28]** Court finds it disingenuous for Zenith to repeatedly complain that "the only thing preventing Zenith from obtaining [FDA] approval is Zenith's failure to make the patent certification" (see Zenith's Reply Br. at 7) without realizing that the only reason that it got as far as it did in the FDA approval process in so little time to begin with is because it was able to "piggy back" on Abbott's testing. Moreover, it has been Zenith's own choice not to make the very patent certifications to the FDA that are now blocking its drug's approval. Finally, the denial of this injunction does not foreclose Zenith's opportunity to express its disagreement with the FDA's decision to close its file on Zenith's ANDA application. Zenith may request an opportunity for a hearing before the FDA regarding its decision. (See Second Rocco Decl., Exh. B)

D. Public Interest Factors

Under Third Circuit law, the Court need not go further in its analysis of the factors to consider on a motion for a preliminary injunction, because Zenith's failure to establish a likelihood of success on the merits and irreparable harm is fatal to its motion. See *Morton, 822 F.2d at 367*. **[*29]** For purposes of thoroughness, however, the Court will discuss those factors briefly.

Zenith's argument that the public will save "massive amounts of money" when generic equivalents of Hytrin are available on the market makes sense on its face; however, it is only persuasive when evaluated in a vacuum. Zenith ignores the fact that the public's interest in having lower-priced (i.e., generic) drugs available to it was already considered and evaluated by Congress when it enacted the Hatch-Waxman Amendments in the first instance. The Amendments emerged as a result of Congress' balancing, on the one hand, the public's interest in ensuring that name-brand pharmaceutical companies have the incentive to make the investments necessary to research and develop new drug products and, on the other hand, the public's interest in having lower-priced, generic copies of those drugs available to it. See H.R. Rep. No. 98-857(I), at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

Zenith, while refusing to follow the procedures set forth in the Hatch-Waxman Amendments, asks the Court to revisit the competing policies on which they were based and determine that Congress got the balance **[*30]** wrong. Clearly, this is an undertaking with which the

Court cannot and will not involve itself. This Court believes that the public interest is best served in this case by a faithful application of the Hatch-Waxman Amendments and of the procedures for generic drug approval contained therein.

E. Balance of Hardships

Much the same argument applies to the balance of hardships between the parties. Zenith argues that "Abbott will suffer no real harm whatsoever" if the Court grants it injunctive relief. Apparently, Zenith forgets that Abbott would, in fact, suffer great harm if this injunction were to issue, as would the other generic companies who have filed the appropriate certifications with respect to Abbott's listed patents, because to grant this injunction would be to sanction Zenith's end-run around the Hatch-Waxman Amendments themselves. Zenith argues that were this injunction to issue, Abbott would not be precluded from bringing a patent infringement suit against it. The Hatch-Waxman Amendments intended for companies such as Abbott to have the right to litigate patent infringement claims against their generic competitors before the generic drug companies are allowed to **[*31]** bring their drugs to market. See *21 U.S.C. § 355*(j)(4)(B)(iii). If Zenith were permitted to enter the market now, Abbott would lose this benefit.

If Abbott were forced to delist the '095 and '207 patents, it would also be placed in a compromised position vis-a-vis other generic competitors seeking to market their versions of Hytrin. In other words, Abbott would lose the right to litigate prior to market-entry any patent infringement claims it might have with respect to the '095 and '207 patents against all of its generic competitors, not just Zenith. Additionally, those companies that are already engaged in patent litigation with Abbott, none of whom have had its generic drug on the market during the pendency of litigation, would also be harmed if this injunction were to issue. These companies have played by the rules of the Hatch-Waxman Amendments and, thus, also have a strong interest in seeing those rules observed. n8

n8 Hatch-Waxman provides that the first generic competitor to successfully challenge a pioneer patent shall have 180 days as the only generic drug on the market. See *21 U.S.C. 355*(j)(4)(B)(IV). The generic company entitled to this period of market exclusivity (presumably one of those companies already engaged in patent litigation with Abbott) could be deprived of this benefit if Zenith's preliminary injunction were to issue. See also *Mova Pharmaceutical, 955 F. Supp. at 131*.

[*32]

IV. CONCLUSION

For the reasons stated herein, the Court determines that Zenith has failed to sustain its burden of proving that injunctive relief is warranted. Accordingly, Zenith's motion for a preliminary injunction must be denied.

JOHN W. BISSELL

United States District Judge

DATED: October 1, 1997

ORDER

For the reasons set forth in the Court's Opinion filed herewith,

It is on this 1st day of October, 1997,

ORDERED that plaintiff's motion for a preliminary injunction be and it hereby is denied.

JOHN W. BISSELL

United States District Judge

EXHIBIT 2

POSITION OF TEVA PHARMACEUTICALS USA INC.
WITH RESPECT TO 180-DAY EXCLUSIVITY FOR MIRTAZAPINE 45 MG TABLETS

The following presents Teva's position with respect to its eligibility for the 180-day exclusivity period for generic mirtazapine 45 mg tablets, and in response to Mylan Pharmaceuticals' May 31, 2002 Citizen Petition. In its petition Mylan requests that FDA reverse its acceptance for filing of Teva's ANDA No. 76-119 for mirtazapine 45 mg tablets, and thereby transfer Teva's 180-day exclusivity period for the 45 mg dosage strength to Mylan. As shown herein, Mylan's petition is meritless and should be denied immediately.[1]

The basis of Mylan's petition is that the Drug Master File (DMF) referred to in Teva's ANDA was not filed by the DMF holder until four days after Teva submitted the ANDA to FDA on February 26, 2001. In the interim, on February 28, 2001, Mylan submitted its ANDA for a 45 mg mirtazapine product, and therefore, according to Mylan, FDA's filing of Teva's ANDA as of its submission date should now be retroactively altered to deprive Teva of its first-to-file status for the 45 mg strength. Mylan's petition exalts form over substance, does not advance the purposes of the refuse to file regulations, and would fundamentally alter FDA's established practices in a way that could lead to an administrative morass of challenges to ANDA filing dates that could further deplete OGD's scarce resources and scramble settled exclusivity expectations.

FDA Is Not Required To Refuse To File An ANDA Based On A Delayed DMF Number

The crux of Mylan's argument is that Teva's ANDA was not "substantially complete" when submitted and that FDA must therefore have refused to file the application. Mylan's position overstates the meaning and purpose of the agency's refuse-to-file regulations and should not be adopted by FDA.

First, the "substantially complete" requirement upon which Mylan relies was designed to avoid "sham" ANDAs – i.e., ANDAs submitted with incomplete or inadequate bioequivalence data that would waste FDA resources and potentially subvert the 180-day exclusivity period incentive. The legislative history, FDA's preambular discussions of the ANDA submission and Paragraph IV Notification requirements, and the regulations themselves, reflect that this "substantially complete" requirement was directed at non-existent or fatally defective bioequivalence data, when used to subvert the Paragraph IV Notification and 180-day exclusivity period mechanisms, and was not intended to encompass minor omissions, or as here, a four day

[1] FDA's protracted delay in responding to this petition and approving all strengths of generic mirtazapine (even though there is no dispute as to Teva's exclusivity for the 15 mg and 30 mg strengths) has cost consumers millions of dollars in unrealized savings, and has prejudiced Teva because its 180-day exclusivity period has been running since December 18, 2002 when the U.S. District Court for the District of New Jersey ruled that Teva's mirtazapine products do not infringe the patents listed in the Orange Book for Remeron brand mirtazapine.

delay in the submission of an otherwise complete and adequate DMF. As the House Report on Hatch-Waxman states,

> The Committee does not intend that [ANDA] applicants be permitted to circumvent this [Paragraph IV] notification requirement by filing sham ANDAs or ANDAs which are substantially incomplete. The Committee intends that the applicant must have made a good faith effort to meet the requirements set forth in paragraph (2)(A) [21 U.S.C. § 355(j)(2)(A)] regarding the contents of an ANDA.
>
> While the Committee does not intend that failure to include a minor piece of information in an ANDA vitiates the effectiveness of the notice required under paragraph (2)(B), an ANDA must include the results of any required bioavailability or bioequivalence tests.

H. Rept. 98-857, Part 1 at 24, 98th Cong. 2d Sess. (June 21, 1984) (emphasis added). FDA's explanation of the "substantially complete" requirement in the preamble to its 1992 final regulations is consistent with the Congressional intent that refusals to file were primarily concerned with bioequivalence data,

> FDA has changed its policies regarding the submission of incomplete ANDAs. Under earlier policy, FDA permitted ANDA applicants to submit ANDAs with bioequivalence study protocols and to provide bioequivalence study data at a later date. This policy has resulted in a significant and unwarranted expenditure of resources in reviewing applications that had little potential for approval. FDA will therefore no longer accept an ANDA that does not contain complete bioequivalence study data if such data are required for approval.

57 Fed. Reg. 17950, 17959 (April 28, 1992) (emphasis added).

Here, Teva clearly made a "good faith effort to meet the requirements set forth in" 21 C.F.R. § 314.94, and the inconsequential delay in the filing of a DMF from overseas cannot be described as anything more than an inadvertent "failure to include a minor piece of information" in its ANDA. Indeed, FDA did in fact accept Teva's ANDA for filing, effective as of the date of submission, and Teva submitted its Paragraph IV Notification in accordance with that acceptance.

Second, FDA unquestionably has the discretion to accept an ANDA even in the absence of a DMF number, and the agency's discretionary decision, nearly two years ago, to accept Teva's ANDA should not now be undermined as Mylan requests. FDA's refuse to file regulations require FDA to accept an ANDA for filing unless one of several enumerated circumstances exists, as described in the regulation. Specifically, section 314.101(b)(2) states that "If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for considering the abbreviated new drug application not to have been received applies, the agency will receive the abbreviated new drug application and notify the applicant in writing."

Importantly, however, the existence of a circumstance described in paragraph (d), such as a delayed DMF number, does not require FDA to refuse to file the application. This is because the conditions described in paragraph (d) only allow, but do not require, FDA to refuse to file an ANDA, whereas the conditions described in paragraph (e) are mandatory bases for a refusal to file. The following table illustrates this crucial distinction:

314.101(d)	314.101(e)
(d) "FDA **may** refuse to file an application **or may** not consider an abbreviated new drug application to be received if any of the following apply: (1) * * * (2) The application is not submitted in the form required under § 314.50 **or** § 314.94. (3) The application or abbreviated application is incomplete because it does not on its face contain information required under...§ 314.50 **or** § 314.94." (Emphasis added).	(e) "The agency **will** refuse to file an application **or will** consider an abbreviated new drug application not to have been received if any of the following applies: (1) the drug product is subject to licensing by FDA [as a biologic]. (2) [the active ingredient is subject to an unexpired NCE exclusivity]. (Emphasis added).

Mylan's incomplete quotation of paragraph (d) – "FDA's regulations state that it '[...] *may not consider an abbreviated new drug application to be received if*...'", Mylan Petition at 4 – misleadingly implies that this provision prohibits FDA from filing an ANDA with a deficiency in any requirement under section 314.94 or 314.50, including a DMF deficiency. Although the regulation may be inartfully drafted, Mylan's interpretation ignores the context, structure, and intent of paragraph (d) and would lead to absurd results.

Paragraph (d) and (e) each address both NDA and ANDA deficiencies, and for the deficiencies addressed in each paragraph the clear intent is to implement refuse-to-file decisions consistently as between NDAs and ANDAs. This is reflected by the use of the use of the term "may" throughout paragraph (d), and the use of the conjunction "or" in the main body of paragraph (d) and in subparagraphs (d)(2) and (d)(3). These structural aspects of the regulation provide the proper context to understand that paragraph (d) is intended to provide FDA with *discretionary* ability to refuse to file *either* an NDA **or** an ANDA where a deficiency under section 314.50 **or** 314.94 exists. This is so notwithstanding that the phrasing of the ANDA portion of paragraph (d) – "may not consider" – would, under Mylan's interpretation, appear to be a prohibition with respect to ANDA deficiencies.

The illogic of Mylan's position is highlighted by the fact that it would require FDA to treat the deficiencies identified under paragraph (d) differently depending on whether the application was an NDA or an ANDA. Thus, for example, under Mylan's approach, an NDA that omits the address of the applicant (a requirement under § 314.50(a)(1)), could be filed by

FDA, but an ANDA with a missing address (also required under § 314.50(a)(1) by reference in § 314.94(a)(1)) would have to be refused for filing. Moreover, if, as Mylan's position presupposes, the purpose of paragraph (d) was to *prohibit* FDA acceptance of ANDAs with any deficiency under section 314.94 and 314.50, FDA certainly would have signaled this purpose more clearly by including ANDA deficiencies under paragraph (e), which by its terms is a mandatory prohibition on FDA acceptance of applications in specified circumstances.

Furthermore, if FDA accepts Mylan's interpretation of paragraph (d), it will create unmanageable administrative burdens on FDA, because the agency will have no choice but to refuse to file every ANDA that has even the most minor of deficiencies under section 314.94 or 314.50. FDA's current practices clearly allow filing despite such deficiencies, and those practices must cease immediately upon a granting of Mylan's petition. As discussed in more detail below, this could result in virtually every ANDA being refused at least once, thereby causing unconscionable confusion and further delays in ANDA review and approval.

Finally, the fact, cited by Mylan's petition (pages 4, 6), that FDA has in the past refused to file ANDAs for, among other reasons, inadequate DMF information is not dispositive here, because RTF decisions are discretionary with respect to DMF information, and presumably the applications from which FDA's statistics were derived presented more serious DMF problems than the four day delay in Teva's otherwise adequate DMF. Moreover, the FDA document cited by Mylan discussing DMF-based refusals to file does not specify how many other deficiencies contributed to any particular RTF decision. Undoubtedly, many such refused ANDAs presented a number of other, more significant problems besides a slightly delayed DMF. Here, Teva's DMF delay was minor, as it was filed within days after the ANDA was submitted, and the DMF itself presented no substantive problems that hindered or delayed FDA's substantive review of the ANDA. FDA should not accept Mylan's invitation to alter Teva's date of filing.

FDA Should Not Retroactively Refuse to File, or Amend The Filing Date, of Teva's ANDA

As shown above, FDA was fully within its authority to accept Teva's ANDA for filing as of the date of submission, notwithstanding the minor delay in identification of the DMF number. If FDA were to now retroactively change that decision on the bases put forth by Mylan, it would not only be egregiously unfair to Teva, but would also effect a fundamental change to FDA's well established practice not to penalize applicants whose ANDAs have minor DMF deficiencies at the time of submission. The result would be to establish a policy that could have negative repercussions both retroactively and prospectively.

For example, it is conceivable that an ANDA and its DMF could be mailed on the same day but, due to geography (many DMFs are from foreign entities) and the mail service selected, the DMF could be delayed in its arrival. During this delay another applicant's subsequently mailed ANDA could arrive. A policy to monitor the exact date of filing of a DMF as a determinant of filing order, makes a process that is already complex, difficult and burdensome even more so. Presumably this is at least one of the reasons why the Office of Generic Drugs has accepted Teva's ANDA without regard to the minor discrepancy in the filing dates. In fact, we understand that it has been long standing OGD practice that, as long as the DMF arrived in "a reasonable period of time" and was available when the application was originally reviewed for

completeness, there would be no issue or cause to refuse the application. Such exercise of FDA's discretionary authority under section 314.101 is reasonable and entirely appropriate and should be adhered to here.

In addition, it would not be surprising if applications with the same DMF circumstances as mirtazapine (i.e., where the application was complete on its face when picked up for review) have already been approved, and exclusivity granted, without regard to the filing date of the DMF. If FDA were to adopt the new approach advocated by Mylan, FDA should expect that numerous Paragraph IV ANDA filers will engage in Freedom of Information Act "fishing expeditions" or other tactics, seeking to uncover minor DMF deficiencies in order to challenge the exclusivity already granted to other companies. This would be particularly problematic if the product had already been commercialized under the exclusivity. Moreover, such applicants seeking to undermine their competitors' first-to-file status will make searching inquiries into other potential deficiencies with respect to the numerous requirements of sections 314.50 and 314.94, and argue that any such minor deficiencies should also be cause to scramble the filing order and exclusivity eligibility of various applications. Indeed, under Mylan's approach, any deficiency in any required element under § 314.94 could form the basis of a retroactive refusal to file. Hence this change in policy will have disastrous consequences both retroactively as well as prospectively. By way of example, if FDA accepts Mylan's interpretation, FDA would be required, without exception, to refuse to file ANDAs with any of the following deficiencies:

- Omission of a table of contents in an archival copy of the ANDA;
- Omission of a cGMP statement;
- Omission or typographical error in the number of an approved suitability petition;
- Non-original signature on application form;
- Missing annotations to the innovator's approved labeling;
- Incorrect patent certification;
- Too few copies of the proposed labeling;
- A missing checklist of enclosures;
- Uncertified field copy; or
- A slight delay in providing translated versions of foreign-language literature references.

Teva submits that no ANDA in the history of Hatch-Waxman has ever been submitted without some minor deficiency in some requirement of section 314.94, and unless the agency is prepared to accept filing challenges based on any deficiency for which a refusal to file *could* be based, and to publicly announce such a policy shift, it should deny Mylan's petition.

Conclusion

Teva's opposition to Mylan's petition should not be construed to mean that Teva does not strongly support meaningful measures to ensure that files are substantially complete for review. We believe it is critical that only those files representing a reasonably complete legal, scientific, and regulatory presentation of the proposed generic product should be accepted for filing. The minor DMF filing date discrepancy that Mylan latches onto here represents nothing more than a

de-minimus oversight that should not affect filing eligibility so long as the DMF number was available to FDA when the application is actually picked up for completeness review.

Based on the foregoing understanding of FDA's regulations and the agency's established discretionary practices, Teva did not believe that the Mylan petition had merit. Given the agency's ubiquitous refrain that ANDA approvals are delayed by the strain on FDA resources due to multitudes of citizen petitions and other regulatory obligations, Teva saw no value to it or the agency of burdening this docket with responsive comments. Given the agency's inability to resolve this longstanding petition, and the resultant delay in public availability of all strengths of otherwise approvable generic mirtazapine products, Teva respectfully submits these comments in the hope of facilitating a very prompt final decision to deny Mylan's petition, and to grant final approval of Teva's mirtazapine ANDA.

EXHIBIT 3

Westlaw

Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2002 WL 433584 (N.D.Ill.)
(Cite as: Not Reported in F.Supp.2d)

Briefs and Other Related Documents
Only the Westlaw citation is currently available.

United States District Court, N.D. Illinois, Eastern Division.

ABBOTT LABORATORIES, an Illinois corporation; Fournier Industrie Et Santé, a French corporation;and Laboratoires Fournier S.A., a French corporation, Plaintiffs,

v.

NOVOPHARM LIMITED, a corporation of the dominion of Canada; and Teva Pharmaceutical Industries Ltd., an Israeli corporation, Defendants.

No. 00 C 2141, 00 C 5094, 01 C 1914.

March 20, 2002.

MEMORANDUM OPINION AND ORDER

DARRAH, District J.

***1** Defendant, Novopharm, filed an Abbreviated New Drug Application ("ANDA") seeking the Food and Drug Administration's ("FDA") approval to market a generic micronized fenofibrate product in three dosage forms. Subsequently, Fournier, the owner of the Curtet Patent, and Abbott, Fournier's exclusive licensee under the Curtet Patent, filed the present actions for each of Novopharm's three proposed dosage forms, alleging that the process described in Novopharm's ANDA and the products produced by that process would infringe the Curtet Patent. The three lawsuits were consolidated. Presently before the Court is Novopharm's Motion for Summary Judgment of Noninfringement.

FACTS

The Curtet Patent has 12 claims. (Def.'s 56.1(a)(3) Statement ¶ 20) Claims 1 and 10 are the only independent claims of the Curtet Patent. Claims 2-9 and 11-12 depend ultimately from claim 1. (Id., at ¶¶ 21-22).

Claim 1 of the Curtet Patent, as originally filed, stated:

A therapeutic composition, presented in the form of gelatin capsules, which is useful especially in the oral treatment of hyperlipidemia and hypercholesterolemia, the said composition containing fenofibrate and a solid surfactant which have been co-micronized. (Def.'s 56.1(a)(3) Statement ¶ 75).

During the Patent's prosecution, the United States Patent and Trademark Office ("PTO") issued an "Office Action", rejecting claim 1 under 35 U.S.C. § 103 as being obvious over Schonafinger *et al.* in view of Schonafinger and Grouiller. (Id. at ¶¶ 76-77).

In July 1989, Fournier submitted an amendment in response to the Office Action. The amendment added the present limitation of "a co-micronized mixture of particles". (Id., at ¶¶ 78-79).

Fournier distinguished the cited prior art from the claimed invention, as amended, on the ground that the prior art did not teach or suggest co-micronization of fenofibrate and a solid surfactant such that co-micronization as claimed resulted in an improvement, namely improved bioavailability. (Def.'s 56.1(a)(3) Statement ¶ 82). In response to the Office Action, Fournier explained to the PTO that "none of the [cited] references alone in any combination thereof teaches or suggests co-micronization of a mixture of fenofibrate and a solid surfactant." (Id., at ¶ 83). Fournier also explained that "none of the [cited] references alone or in any combination thereof teaches or suggests ... that by co-micronizing said mixture a lower daily dosage may be administered because the bioavailability of fenofibrate is significantly and unexpectedly increased." (Id., at ¶ 84).

The amendment also stated that "Groullier et al. [does not] teach or suggest co-micronization of a mixture of fenofibrate with a solid surfactant to produce particles having a diameter of less than 15 mm." (Def.'s 56.1(a)(3) Statement ¶ 85) It further differentiated Schonafinger, stating that "Schonafinger ('743), thus, does not teach or suggest co-micronization of fenofibrate with a solid surfactant." (Id., at ¶ 86). Fournier stated, "none of [the references cited in the Office Action] alone or in any combination thereof teaches or suggests co-micronization of a mixture of fenofibrate and a solid surfactant, wherein the particles in said co-micronized mixture have mean diameter less than 15 um" (Id., at ¶ 88).

***2** The amendment also addressed dissolution, stating

that it could "be seen in all instances fenofibrate in the co-micronized mixture dissolves about 20-25% faster than fenofibrate that is micronized prior to mixing with micronized solid surfactant." (Def.'s 56.1(a)(3) Statement ¶ 91). Fournier stated that "none of [the cited references] teach or suggest that co-micronizing fenofibrate with a solid surfactant will increase the rate at which fenofibrate dissolves compared to the rate at which micronized fenofibrate mixed with micronized solid surfactant dissolves...." (Id., at ¶ 93).

Following the amendments and above arguments, the PTO allowed all of the claims. (Def.'s 56.1(a)(3) Statement ¶ 96)

Claim 1 of the Curtet Patent states, in its entirety:
A therapeutic composition, which is presented in the form of gelatin capsules and which is useful especially in the oral treatment of hyperlipidemia and hypocholesterolemia, said composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant, wherein the mean particle size of said co-micronized mixture is less than 15 um (Id., at ¶ 23).

Claim 8 of the Curtet Patent, which depends on claim 1, states:
A method for the manufacture of a therapeutic composition according to claim 1, which comprises:
(i) intimately mixing and then co-micronizing the fenofibrate and solid surfactant,
(ii) adding lactose and starch to the mixture obtained,
(iii) converting the whole to granules in the presence of water,
(iv) drying the granules until they contain no more than 1% of water,
(v) grading the granules,
(vi) adding polyvinylpyrrolidone and magnesium stearate, and
(vii) filling gelatin capsules. (Def.s 56.1(a)(3) Statement ¶ 24).

Claim 10 of the Curtet Patent states:
A method for improving the bioavailablilty of fenofibrate *in vivo*, which comprises co-micronization of the fenofibrate and a solid surfactant, the said co-micronization being carried out by the micronization of a fenofibrate/solid surfactant mixture until the particle size of the powder obtained is less than 15 um. (Def.'s 56.1(a)(3) Statement ¶ 26).

The Curtet Patent states a dosage form of one 300 mg fenofibrate gelatin capsule had been proposed. (Def.'s 56.1(a)(3) Statement ¶ 36). The Curtet Patent also states:
It is known that micronization of an active principle is capable of improving the dissolution of the said active principle in vivo, and hence its bioavailability. It is known that the addition of a surfactant excipient to a formulation of an active principle is capable of improving absorption and consequently the bioavailability of the said active principle. (Id., at ¶ 37; Curtet Patent)

The only "active principle" discussed in the Curtet Patent is fenofibrate. (Id., at ¶ 38).

The Curtet Patent states that it is the "co-micronization of fenofibrate and a solid surfactant (i.e., the micronization of an intimate mixture of fenofibrate and a solid surfactant) makes it possible to improve the bioavailability of the fenofibrate to a significantly greater extent than that which would be achieved either by adding a surfactant [to fenofibrate], or by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant." (Def.'s 56.1(a)(3) Statement ¶¶ 43-44; Curtet Patent)

*3 The Curtet Patent states that the surfactant "will be selected from solid surfactants so that it can be co-micronized with fenofibrate." (Def.'s 56.1(a)(3) Statement ¶ 56). Sodium lauryl sulfate ("SLS") is the only example of a solid surfactant disclosed in the Curtet patent. (Id., at ¶ 58). "The micronization of the fenofibrate and the solid surfactant will be advantageously carried out in an accelerated air-jet mill...." Furthermore, "[t]o obtain a powder which can be formulated into gelatin capsules , lactose may be added to the co-micronizate of fenofibrate and solid surfactant." (Curtet Patent)

The Curtet Patent sets forth "a method for the preparation of a therapeutic composition containing fenofibrate and a solid surfactant is recommended which comprises: (i) intimately mixing and then co-micronizing the fenofibrate and solid surfactant. (ii) adding lactose and starch to the mixture obtained ." It also provides "Preparative Examples" to aid in understanding the patent and to show that the patent is non-obvious. For example, "Preparation I" states: "The fenofibrate/sodium lauryl-sulfate mixture is co-micronized in an air-jet micronizer to give a powder with a medium particle size of 3 um. The lactose and the starch are then added to this powder ..." (Def.'s

56.1(a)(3) Statement ¶¶ 45-46, 60; Curtet Patent).

In December 1999, Fournier filed for reexamination of the Curtet Patent. (Def.'s 56.1(a)(3) Statement ¶ 97). The request for reexamination stated that an article entitled, "Microbroyage et Dissolution", authored by Georges Boullay, raised a substantial new question of the patentability of the claims of the Curtet Patent. (Id., at ¶ 98) The PTO granted reexamination in early 2000 (Id., at ¶ 99).

During the reexamination, Fournier stated, "unlike fenofibrate which exhibits unexpectedly rapid dissolution when co-micronized with surfactant compared with fenofibrate micronized alone, [other fibrates] show no statistically significant increase in dissolution." (Def.'s 56.1(a)(3) Statement ¶ 102). A declaration by Philippe Reginault, one of the inventors, submitted by Fournier, compared "co-micronized fibrates" with "the corresponding fibrate that was first micronized and then mixed with a micronized solid surfactant". (Id., at ¶ 105). In May 2001, the PTO concluded the reexamination proceeding and upheld the patent. (Id., at ¶ 106).

Descriptions of the process steps that Novopharm employs for manufacturing all three dosage forms of its proposed products have been submitted to the FDA in connection with Novopharm's NDA. (Def.'s 56.1(a)(3) Statement ¶ 108). According to Novopharm's process, fenofibrate is first pre-micronized on its own and in the absence of any other ingredient. (Id., at ¶ 109). The pre-micronized fenofibrate is then dry mixed with lactose monohydrate, pregelatinized starch, croscarmellose sodium and crosspovidone (Id., at ¶ 110).

*4 Separately, for the above dry mixing step, povidone and sodium lauryl-sulfate are dissolved in water to form a granulating solution. (Def.'s 56.1(a)(3) Statement ¶ 111) The granulating solution is then added to the dry fenofibrate mixture. (Id., at ¶ 112). The mixture of the granulating solution and the dry fenofibrate mixture resulting from the previous step is subjected to a wet granulation process involving the addition of more water and thorough mixing. (Id., at ¶ 113).

Following wet granulation, the mixture is dried, weighed, and assessed for "loss on drying". (Def.'s 56.1(a)(3) Statement ¶ 114). The dried, granulated mixture is then dry blended with additional croscarmellose sodium, crosspovidone, and magnesium stearate to produce granules that can pass through a # 16 mesh screen. (Id., at ¶ 115) The granulated mixture is then blended again, weighed, and stored for eventual encapsulation into gelatin capsules. (Id., at ¶ 117).

LEGAL STANDARDS

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact." Fed.R.Civ.P. 56(c); *see also* *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). All the evidence and the reasonable inferences that may be drawn from the evidence are viewed in the light most favorable to the nonmovant. *Miller v. American Family Mutual Ins. Co.*, 203 F.3d 997, 1003 (7th Cir.2000). Summary judgment may be granted when no "reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

A patent infringement analysis consists of two steps. In the first step, the meaning and scope of the patent claims asserted to be infringed are determined. This is commonly referred to as claim construction. The second step entails proving the infringement by comparing the properly construed claims to the device accused of infringing. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995) (*Markman*).

A. Claim Construction

In construing the claims of a patent, the court reviews the extrinsic evidence of record. This evidence includes the claims of the patent, the specifications, and the prosecution history. *See* *Bell Atlantic Network Serv., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1267 (Fed.Cir.2001) (*Covad*).

Generally, all of the terms in a patent claim are given their plain, ordinary, and accustomed meaning to one of ordinary skill in the relevant art. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed.Cir.2001) (*Rexnord*). Unless compelled to do otherwise, a court should give a claim term the full range of its ordinary meaning as understood by one of ordinary skill in the relevant art. *Rexnord*, 274 F.3d at 1342. Dictionaries and technical treatises, while extrinsic evidence, may also be considered along with the intrinsic evidence when determining the ordinary meaning of claim terms. *Covad*, 262 F.3d at 1267.

***5** Once the plain meaning of a disputed claim term is ascertained, the court must examine the written description and any drawings to confirm that the patentee's use of the disputed term is consistent with the meaning given to such term by the court. *Rexnord*, 274 F.3d at 1342. The written description and any drawings are reviewed to determine if the patentee chose to set forth an explicit definition that is different in scope from that of the ordinary meaning. In addition, the court examines the written description and drawings to determine whether the preferred embodiment falls within the scope of a construed claim because a claim construction that would exclude the preferred embodiment 'is rarely, if ever, correct and would require highly persuasive evidentiary support'. *Rexnord*, 274 F.3d at 1342, quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed.Cir.1996). Furthermore, the written description and drawings are reviewed to determine whether the patentee disclaimed any subject matter or has otherwise limited the scope of the claims. *Rexnord*, 274 F.3d at 1342.

Lastly, the court reviews the prosecution history because a statement made during the prosecution of a patent may affect the scope of the invention and the meaning of the claims. *Covad*, 262 F.3d at 1268.

B. Infringement

"In order to prove infringement, a patentee must show that every limitation of the claims asserted to be infringed is found in the accused device." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed.Cir.1997). As a matter of law, an accused device cannot infringe if even a single limitation is not satisfied. *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1349 (Fed.Cir.1998).

Infringement is proved either literally or under the doctrine of equivalents. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed.Cir.1998). "To establish literal infringement, every limitation set forth in a claim must be found in the accused product, exactly." *Southwall Technologies, Inc. v. Cardinall IG Co.*, 54 F.3d 1570, 1576 (Fed.Cir.1995).

Under the doctrine of equivalents, an accused device infringes only if it possesses all of the limitations of the claim either literally or equivalently. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed.Cir.1998). The "doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson v. Davis*, 570 U.S. 17, 29 (1997) (*Davis*). Furthermore, application of the doctrine cannot be used to erase limitations from the claim. *Davis*, 570 U.S. at 29. The differences between the accused device and the claim limitation must be "insubstantial" to possess an equivalent claim limitation. *Desper*, 157 F.3d at 1338. This analysis generally turns on whether the accused device performs substantially the same function in substantially the same way to achieve substantially the same result. *Alpex Computer Corp. v. Nintendo Co.*, 102 F.3d 1214, 1222 (1996).

***6** Another factor affecting the issue of infringement is the doctrine of prosecution history estoppel. The doctrine of prosecution history estoppel prohibits the application of equivalents and precludes a patentee from obtaining coverage under the doctrine of equivalents of subject matter that was relinquished during the prosecution of the patent. *General Elec. Co. v. Nintendo Co.*, 179 F.3d 1350, 1362 (Fed.Cir.1999).

Prosecution history estoppel occurs as a result of arguments made during prosecution of the patent that show a clear and unmistakable surrender of subject matter through amendments made to overcome patentability rejections (*Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241, 1251 (Fed.Cir.2000)) or through unequivocal arguments or assertions made during patent prosecution (*Desper Prods., Inc. v. Qsound Labs*, 157 F.3d 1325, 1338 (Fed.Cir.1998)) and/or reexamination (*Intermatic Inc. v. Lamson & Sessions Co.*, 273 F.3d 1355, 1366 (Fed.Cir.2001)). The determination of what subject matter was surrendered is an objective one, measured from the vantage point of what a competitor reasonably would conclude the patentee had relinquished in order to secure the patent. *Augustine Medical, Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1299 (Fed.Cir.1999).

ISSUES

A. Claim Construction

The parties dispute the construction of the term "co-micronized". Plaintiffs argue that the term should be given its "ordinary meaning" of "micronized with or together". Defendant argues that the term should be construed narrowly to mean that "fenofibrate and a solid surfactant have been micronized together and in the absence of any other excipients".

In essence, the parties do not disagree as to the common meaning of the term "co-micronized". Both parties agree that the common meaning is construed to mean "micronized with or together". This common meaning is supported by the definitions of the parts of the word. "Co-" is defined the same as "con-"-"a prefix meaning with or together". Dorland's Illustrated Medical Dictionary 368, 389 (29th ed.2000). "Micronize" is defined as "to reduce to a fine powder; to reduce to particles a micron in diameter" Dorland's Illustrated Medical Dictionary 1112 (29th ed.2000). Accordingly, the ordinary meaning of the term "co-micronized" would be "to reduce to a fine powder [micronize] with or together".

Defendant argues that the claim language, specification, and prosecution history support a more narrow definition to include that only fenofibrate and a solid surfactant have been micronized together in the absence of any other excipients. Plaintiff argues that Defendant is impermissibly reading a limitation into the claim from the specification.

The term "co-micronize" or a derivative thereof, i.e., co-micronizing, are used in multiple claims, including claims 1, 8, and 10. In each of these claims, a mixture of fenofibrate and a solid surfactant are micronized together. Claim 10 also refers to the micronization of a "fenofibrate/solid surfactant mixture". No other materials or excipients are identified as being part of and of these mixtures.

*7 The term "co-micronize" or its derivatives are also used throughout the specification. For example, the specification states, in pertinent part, that it "has now been discovered that the co-micronization of fenofibrate and a solid surfactant (i.e., the micronization of an intimate mixture of fenofibrate and a solid surfactant) makes it possible to improve the bioavailability ... than that which would be achieved either by adding a surfactant, or by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant." Through this language, Plaintiff distinguished its co-micronized mixture of fenofibrate and a solid surfactant from mixtures obtained by adding a surfactant to fenofibrate, or micronizing fenofibrate by itself, and/or mixing separately micronized fenofibrate and surfactant. By distinguishing its co-micronized mixture from these types of mixtures, Plaintiff's co-micronized mixture cannot include such mixtures. *See* O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1581 (Fed.Cir.1997) (description that distinguished claim over prior art narrowed construction of disputed term). In all of the examples for preparing the product, fenofibrate and a solid surfactant are the only materials micronized together. After the co-micronization, other excipients are added.

During the prosecution of the Curtet Patent and the subsequent reexamination. Plaintiff repeatedly alleged that prior art did not teach or suggest co-micronization of a mixture of fenofibrate and a solid surfactant. Furthermore, Plaintiff stated that fenofibrate in the co-micronized mixture dissolves faster than fenofibrate dissolves when micronized fenofibrate is mixed with micronized solid surfactants. The prosecution history demonstrates that Plaintiff distinguished its claims, in part, on the fact that fenofibrate and a solid surfactant would be micronized together. In every instance, no other materials are included in this co-micronization. Furthermore, fenofibrate and a solid surfactant are the only materials identified in reference to the "co-micronized mixture".

The above demonstrates that Plaintiff micronizes, together, fenofibrate and a solid surfactant. The claims, description, and prosecution history do not indicate that anything other than fenofibrate and a solid surfactant are micronized. Furthermore, the description and prosecution history indicate that one of the distinguishing elements of this Patent is the co-micronization of a fenofibrate/solid surfactant mixture. No other excipient is identified as part of this mixture.

In light of the above, one skilled in the art reading the claims, description, and prosecution history would conclude that the term "co-micronize" in claims 1 and 10 does not encompass co-microzination of excipients other than fenofibrate and a solid surfactant.

Based on the above, the term "co-micronized" is construed to mean that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients.

***8** Defendant also seeks to limit the construction of the phrase "fenofibrate/solid surfactant mixture" in claim 10 to exclude any other ingredients other than fenofibrate and solid surfactant. Plaintiff does not dispute this construction.

"Mixture" is defined as "a combination of different drugs or ingredients". Dorland's Illustrated Medical

Dictionary 1122 (29th ed.2000). Accordingly, a fenofibrate/solid surfactant mixture would be defined as a combination of fenofibrate and solid surfactant. No other materials are included in the description of the mixture; and the claims, patent description, and prosecution history support the conclusion that no other materials are included in the mixture.

Defendant also seeks to limit the phrase "mixture of particles of fenofibrate and a solid surfactant" to mean a "mixture wholly of fenofibrate and a solid surfactant, to the exclusion of any other excipients". Plaintiff opposes such construction, arguing that the phrase is properly construed to mean "a resultant mixture composed of(but not necessarily wholly of) particles that are composed of (but not necessarily wholly of) fenofibrate and a solid surfactant"

"Of" is defined as "a function word to indicate the material, parts, or elements composing something". Webster's Third New Int'l Dictionary 1565 (3rd ed.1986).

In a similar claim, the Eastern District Court of New York construed the language 'net supporters made of PFA, FEP or EPE' to mean that the 'net supporters must be made wholly of PFA, FEP or EPE, and cannot include any other fluorocarbon resin....' *Pall Corp. v. PTI Tech. Inc.*, 259 F.3d 1383, 1390 (Fed.Cir.2001) (*Pall*), quoting *Pall Corp v. PTI Techs*, Nos. CV-97-1134, CV-98-2871 (E.D.N.Y. Dec. 22, 1999). On appeal, the parties did not dispute this claim construction, and the Federal Circuit "agree[d] with the district court's claim construction requiring the net supporters to be made of 100% of one of the recited ... resins." *Pall*, 259 F.3d at 1390.

In light of the claim language, and the patent description and prosecution history discussed above, the phrase "mixture of particles of fenofibrate and a solid surfactant" means a "mixture of particles wholly of fenofibrate and a solid surfactant".

B. Infringement

1. Literal Infringement

In order to establish literal infringement, Plaintiff must demonstrate that every limitation in a claim is exactly found in the accused device. *Southwall*, 54 F.3d at 1576. As to claim one, the parties do not dispute that fenofibrate and a solid surfactant are not micronized together in the absence of other excipients in Defendant's product. Accordingly, Defendant does not literally infringe either claim 1 or 10 of the Curtet Patent.

2. Doctrine of Equivalents

Defendant first argues that Plaintiff is estopped from asserting the doctrine of equivalents as to claim 1 and 10's co-microzination limitation.

During the prosecution of the Curtet Patent, Plaintiff amended claim 1, changing the original phrase of "the said composition containing fenofibrate and a solid surfactant which have been co-micronized" to state "said composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant, wherein the mean particle size of said co-micronized mixture is less than 15 um." Plaintiff distinguished the prior art from the claimed invention, in part, on the ground that prior art did not teach or suggest co-micronization of fenofibrate and a solid surfactant such that the co-micronization resulted in an improvement in bioavailability. Plaintiff further stated that "none of the [cited] references alone or in combination thereof teaches or suggests ... that co-micronizing said mixture a lower daily dosage may be administered because the bioavailability of fenofibrate is significantly and unexpectedly increased."

***9** These arguments clearly demonstrate that Plaintiff distinguished its invention from prior art because of the increase in bioavailability obtained through co-micronization of fenofibrate and a solid surfactant.

In the Curtet Patent Plaintiff addressed this increase in bioavailability and distinguished its product and process from those achieved by adding a surfactant or by micronizing the fenofibrate on its own or by intimately mixing the separately micronized fenofibrate and surfactant.

During the reexamination of the Curtet Patent, Plaintiff further distinguished co-micronization of fenofibrate and a solid surfactant to fenofibrate that is micronized alone when discussing dissolution rates in order to distinguish the Curtet Patent

Based on the arguments made during the prosecution of the patent as to increased bioavailability, patent language as to bioavailability, and the arguments made during reexamination, a competitor would reasonably conclude that Plaintiff relinquished a product and process that involved either adding a

surfactant by itself or by micronizing the fenofibrate on its own or by intimately mixing the separately micronized fenofibrate and surfactant.

In the instant case, it is undisputed that Defendant pre-micronizes fenofibrate by itself. The above demonstrates that Plaintiff specifically distinguished its co-micronized product and co-micronization process from those obtained from micronizing fenofibrate by itself, as done by Defendant. Accordingly, Plaintiff cannot establish infringement under the doctrine of equivalents for claims 1 or 10. *See Cole v. Kimerbly-Clark Corp.*, 102 F.3d 524, 532 (Fed.Cir.1997) (affirming district court's finding that defendant's accused products did not infringe under the doctrine of equivalents based upon the patent's prosecution history during which plaintiff relinquished coverage to obtain its patent); *Builders Concrete, Inc. v. Bremerton Concrete Products Co.*, 757 F.2d 255, 260 (Fed.Cir.1985)

CONCLUSION

For the forgoing reasons, Novopharm's Motion for Summary Judgment of Noninfringement is granted.

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Briefs and Other Related Documents (Back to top)

- 2002 WL 32812030 (Trial Pleading) Answer, Affirmative Defense, and Counterclaim (Jul. 14, 2002)
- 2002 WL 32450765 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Motion for Clarification that the above Captioned Cases Have Been Consolidated ""For All Purposes" (Apr. 29, 2002)
- 2002 WL 32450759 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Unopposed Motion for Leave to File Joint Response to Novopharm's Summary Judgmen Brief in Excess of Fifteen Pages (Jan. 18, 2002)
- 2001 WL 34769471 (Trial Pleading) Answer, Affirmative Defense, and Counterclaim (Apr. 12, 2001)
- 2001 WL 34666941 (Trial Pleading) Complaint (Mar. 19, 2001)
- 2001 WL 34769468 (Trial Pleading) Complaint (Mar. 19, 2001)
- 1:01CV01914 (Docket) (Mar. 19, 2001)
- 2000 WL 34504428 (Trial Pleading) Answer, Affirmative Defense, and Counterclaim (Sep. 20, 2000)
- 2000 WL 34443426 (Trial Pleading) Complaint (Aug. 18, 2000)
- 2000 WL 34504421 (Trial Pleading) Complaint (Aug. 18, 2000)
- 1:00CV05094 (Docket) (Aug. 18, 2000)
- 2000 WL 34504416 (Trial Pleading) Amended Complaint (Jun. 16, 2000)
- 2000 WL 34442985 (Trial Pleading) Complaint (Apr. 07, 2000)
- 1:00CV02141 (Docket) (Apr. 07, 2000)

END OF DOCUMENT

EXHIBIT 4

Westlaw

Slip Copy
Slip Copy, 2005 WL 3418407 (D.Del.)
(Cite as: Slip Copy)

Only the Westlaw citation is currently available.

United States District Court,D. Delaware.
USA VIDEO TECHNOLOGY CORPORATION, Plaintiff,
v.
MOVIELINK, LLC, Defendant.
No. Civ.A.03 368 KAJ.

Dec. 13, 2005.

Richard D. Kirk, The Bayard Firm, Wilmington, DE, for Plaintiff
John G. Day, Steven J. Balick, Ashby & Geddes, Wilmington, DE, for Defendant.

MEMORANDUM ORDER

JORDAN, J.

I. INTRODUCTION

***1** Plaintiff, USA Video Technology Corporation ("USVO"), brought this patent infringement suit against defendant, Movielink, LLC ("Movielink"). In an opinion dated January 28, 2005, I granted Movielink's Motion for Summary Judgment of Noninfringement of U.S. Patent No. 5,130,792 (issued July 14, 1992) (the " '792 patent"). *USA Video Tech. Corp. v. Movielink LLC*, 354 F.Supp.2d 507 (D.Del.2005). Presently before me is Movielink's Motion for Partial Attorneys' Fees and Costs Pursuant to 35 U.S.C. § 285 and 28 U.S.C. § 1927 (Docket Item ["D.I."] 174; the "Motion"). For the following reasons, the Motion is denied.

II. BACKGROUND [FN1]

FN1. A detailed description of the technology disclosed in the '792 patent was set forth in the summary judgment opinion. *USA Video*, 354 F.Supp.2d at 509-11.

"The '792 patent discloses a variant of what is commonly known as 'video-on-demand' technology. More specifically, it discloses a system and method for transferring a video program for display at a remote location." *USA Video*, 354 F.Supp.2d at 509; *see* '792 patent, col. 1, lines 7-9.

USVO filed the complaint in this matter on April 10, 2003, alleging that Movielink infringed the '792 patent by direct literal infringement, by inducing infringement, by contributing to infringement, and by infringement under the doctrine of equivalents. (D.I. 1 at ¶ 20.) At that time, "Movielink was utilizing the Big-Foot network originally launched in November 2002" to operate its internet-based movie download system. (D.I. 142 at 14.) In 2004, Movielink retired the Big-Foot network system and replaced it with the Multi-CDN system, and USVO withdrew its claims against the Big-Foot system. *USA Video*, 354 F.Supp.2d at 515 n. 6. USVO continued to assert that Movielink's Multi-CDN system infringed the '792 patent.

In the summary judgment opinion, I addressed the issues of claim construction and direct infringement by the Multi-CDN system. [FN2] *USA Video*, 354 F.Supp.2d at 513-523. Claim 1 of the '792 patent includes the following limitation: "wherein said distribution interface initiates connections over the telephone network with remote locations in response to requests received by said request interface." '792 patent, col. 7, lines 52-56 (emphasis added). After construing "initiates" to mean "begins," I concluded that the Multi-CDN system did not literally infringe claim 1 because connections were initiated by the user computer rather than by a distribution interface as required by the claim. *USA Video*, 354 F.Supp.2d at 514-20. Furthermore, USVO added this limitation during patent prosecution and failed to rebut [FN3] the presumption that it had "surrendered all territory between the original claim limitation and the amended claim limitation." *Id.* at 521-22 (quoting *Festo Corp. V. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367 (Fed.Cir.2003)). Therefore, USVO was estopped from asserting infringement under the doctrine of equivalents. *Id.* at 522. Based on these conclusions, I granted Movielink's Motion for Summary Judgment of Noninfringement. *Id.* at 523.

FN2. In its opposition to Movielink's summary judgment motion, USVO "admitted that indirect infringement was not at issue." *USA Video*, 354 F.Supp.2d at 523.

FN3. Rather than squarely addressing the issue, USVO argued that infringement under the doctrine of equivalents was "not ripe for determination." *USA Video*, 354 F.Supp.2d at 522. Because the issue "was pled by USVO" and "appropriately briefed and argued by Movielink," I disagreed. *Id.*

*2 Movielink now asserts that the claims against the Big-Foot system and the claims of infringement under the doctrine of equivalents were frivolous, justifying an award of attorneys' fees and costs. Movielink presents the following facts to support that assertion. First, in response to Movielink's interrogatory dated February 10, 2004 that asked for an element by element explanation of how Movielink's system infringed the '792 patent, USVO described the Movielink system but failed to specifically identify how that system met the "initiates connections" limitation discussed above. (D.I. 139, Ex. AA at 7.) The response recited the '792 claim language and then stated: "As presently advised, Movielink's system delivers videos to customers connected to Movielink through a switched telephone network. The Movielink system transmits the movies in compressed form in less time than is required to view the programs in real time." (*Id.*)

Second, during the depositions of USVO's president, USVO's in-house counsel, and an attorney who was USVO's lawyer when the complaint was filed, each of the witnesses asserted the attorney-client privilege and work product protection in response to questions about the pre-filing investigation of Movielink's system and the factual basis for USVO's infringement claims. (D.I. 139, Ex. U at 81-92, Ex. V at 73:22-74:21, 77:20-79:8; D.I. 176, Ex. B at 37:15-39:23.) Also, USVO's in-house counsel stated in his deposition that USVO based conclusions on public documents about Movielink (D.I. 139, Ex. V at 70:2-16, 77:20-79:8), but USVO produced no such documents in discovery (D.I. 175 at 8).

Third, in a letter dated August 31, 2004, USVO asked the court to compel additional discovery in the form of source code, supporting documentation, and additional depositions. (D.I. 95.)

Fourth, USVO's expert report dated September 25, 2004 did not include any analysis of infringement by the Big-Foot system. (D.I. 175 at 10.) USVO did not withdraw its claims against the Big-Foot system until after Movielink moved for summary judgment on October 25, 2004. *See* *USA Video*, 354 F.Supp.2d at 515 n. 6.

Fifth, in September 2002, a lawyer who later represented USVO in this litigation was quoted in a newspaper article discussing the '792 patent, saying USVO "would have some burden to show that modern data-driven systems are equivalent to the patent's telephone-switched systems." (D.I. 176, Ex. C.) According to the article, that lawyer also said that the patent refers to an old-fashioned telephone-switching network, and that seems to put Internet delivery of video beyond the literal terms of the patent. (*Id.*)

Sixth, USVO's expert did not address infringement under the doctrine of equivalents and said he was unfamiliar with the doctrine. (D.I. 176, Ex. A at 29:2-5.)

Based on these facts, Movielink seeks an award of attorneys' fees and costs from USVO. under 35 U.S.C. § 285, and, under 28 U.S.C. § 1927, from the law firm representing USVO. [FN4]

FN4. Movielink also mentions in passing the standard for awarding sanctions under the court's inherent power to defend the judicial process against abuse, but then seems to argue, incorrectly, that § 1927 is an example of inherent power. (D.I. 175 at 18-19.) To the extent that the Motion is based on the court's inherent power, it is untimely because it was filed after final judgment. *Prosser v. Prosser*, 186 F.3d 403, 405-06 (3d Cir.1999). Likewise, to the extent Movielink intended to base its Motion on Federal Rule of Civil Procedure 11 (*see* D.I. 175 at 19 n. 11), the Motion is untimely *Id.* at 405.

III. STANDARD OF REVIEW

A. *Section 285*

*3 The patent statute provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. "[S]uch exceptional circumstances include ... misconduct during litigation, vexatious or unjustified litigation, or a frivolous suit." *Baver Aktiengesellschaft v. Duphar Int'l Research B.V.*, 738 F.2d 1237, 1242 (Fed.Cir.1984) (citations omitted); *see also* *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295,

1304 (Fed.Cir.2004). The moving party must prove that the case is exceptional by clear and convincing evidence. *Stephens v. Tech Int'l, Inc.*, 393 F.3d 1269, 1273 (Fed.Cir.2004). To show that a lawsuit was frivolous, the moving party must show that "the patentee knew or, on reasonable investigation, should have known [the suit] was baseless." *Id.* at 1273-74. If the moving party proves that the case is exceptional, the court must then decide whether an award of fees is appropriate. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1328 (Fed.Cir.2003)

B. *Section 1927*

"Any attorney ... who so multiplies the proceedings in any case as to increase costs unreasonably and vexatiously may be required by the court to satisfy personally the excess costs, expenses, and attorneys' fees reasonably incurred because of such conduct." 28 U.S.C. § 1927. "[S]anctions [under § 1927] are intended to deter an attorney from intentionally and unnecessarily delaying judicial proceedings, and they are limited to the costs that result from such delay." *LaSalle Nat'l Bank v. First Conn. Holding Group, L.L.C.*, 287 F.3d 279, 288 (3d Cir.2002). "[C]ourts should exercise this sanctioning power only in instances of a serious and studied disregard for the orderly process of justice." *Id.* (quoting *Ford v. Temple Hosp.*, 790 F.2d 342, 347 (3d Cir.1986)). "[S]anctions may not be imposed under § 1927 absent a finding that counsel's conduct resulted from bad faith, rather than misunderstanding, bad judgment, or well-intentioned zeal." *Id.* at 289. Such conduct "must be of an egregious nature, stamped by bad faith that is violative of recognized standards in the conduct of litigation." *Id.* (quoting *Baker Indus. Inc. v. Cerberus, Ltd.*, 764 F.2d 204, 208 (3d Cir.1985)).

IV. DISCUSSION

Movielink contends that USVO's claims of infringement by the Big-Foot system and infringement under the doctrine of equivalents were frivolous, and, therefore, that this case is exceptional and that USVO and its attorneys acted in bad faith. Because the evidence fails to support those conclusions, I will deny the Motion.

A. *The Big-Foot System*

1. *Section 285*

When a "patentee is manifestly unreasonable in assessing infringement, while continuing to assert infringement in court, an inference is proper of bad faith." *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 811 (Fed.Cir.1990). In *Eltech*, the district court awarded sanctions based on affirmative evidence that the patentee knew, more than a year before filing its amended complaint, that the accused infringer was using a noninfringing method, and that the patentee withheld a report that would apparently have confirmed that fact. *Eltech Sys. Corp. v. PPG Indus., Inc.*, 710 F.Supp. 622, 636-37 (W.D.La.1988). By contrast, even when a patentee's pre-filing investigation is "not ideal," an award under § 285 is not appropriate when the conduct "does not rise to the level of bad faith litigation or gross negligence." *Q-Pharma, Inc. v. Andrew Jergens Corp.*, No. C01-1312P, 2002 U.S. Dist. LEXIS 27222, at *15 (W.D.Wash. Nov. 18, 2002), *aff'd* *Q-Pharma*, 360 F.3d 1295.

***4** Here, Movielink asserts that USVO knew or should have known that the infringement claim against the Big-Foot system was baseless, making this an exceptional case under § 285. Movielink's conclusion is based on the following four allegations. First, in response to the February 10, 2004 interrogatory, which at that time referred to the Big-Foot system, "USVO intentionally skipped over the 'initiates connection' limitation." (D.I. 175 at 20-21.) Second, USVO witnesses asserted attorney-client privilege and work product protection when asked about USVO's pre-filing investigation or infringement position, showing either that no pre-filing investigation occurred or that the investigation was unfavorable to USVO's position. (*Id.* at 23-25.) Third, on August 31, 2004, USVO "lacked any basis for alleging infringement," so it asked the court to require additional discovery in the form of source code, supporting documentation, and additional depositions. (*Id.* at 21.) Fourth, USVO presented no expert testimony on infringement by the Big-Foot system. (*Id.*) According to Movielink, these facts show that USVO never had a basis for asserting its patent against the Big-Foot system, making the suit frivolous and justifying a fee award under § 285.

Unlike the defendant in *Eltech*, Movielink has failed to show that USVO had no basis for its suit. Indeed, the factual record here is wholly inadequate to support the requested relief. On the first point, there is no support for Movielink's conclusion that USVO's interrogatory response was intentionally deficient or

misleading. USVO's response fails to address every claim limitation, but this failure does not amount to clear and convincing evidence showing that USVO had no infringement theory and pursued the claim in bad faith.

Second, there is no evidence that the assertion of privilege by USVO witnesses was made in bad faith to cover for a lack of investigation or lack of an infringement theory. Movielink's argument at this late date that these witnesses improperly asserted attorney-client privilege (*id.* at 24) fails to address work product protection and, more importantly, simply fails to show that USVO lacked a basis for asserting infringement.

Third, USVO's discovery request shows only that it was still seeking evidence to support its case, not that it lacked any basis for alleging infringement.

Fourth, USVO concedes that it discovered in July 2004 that the Big-Foot system had been retired (D.I. 186 at ¶ 6), and so its decision not to include it in the infringement analysis of September 25 does not show that it had no basis for asserting infringement in the first place. Rather it is consistent with USVO's assertion that the claim against a then-retired system was dropped for economic reasons. (D.I. 184 at 7.)

Thus, Movielink has failed to show that USVO had no basis for asserting its patent against the Big-Foot system when it filed suit. [FN5]

FN5. As the moving party, Movielink's failure to support its assertions requires me to deny the Motion. I note that, as in *Q-Pharma*, 360 F.3d at 1301, USVO "flatly rebuts [Movielink's] argument" with declarations from its attorneys alleging substantial pre-filing investigation. (*See* D.I. 187 at ¶ ¶ 6-12; D.I. 188 at ¶ ¶ 4-11; D.I. 189 at ¶ 6.)

On a related issue, Movielink also contends that USVO's failure to drop the Big-Foot system claims until after Movielink's summary judgment motion, when USVO allegedly knew by July 2004 that the system was retired, is evidence that USVO maintained this lawsuit in bad faith. However, USVO's discovery that the Big-Foot system was retired did not signal the end of the infringement claim against that system. Movielink's argument that the claim needed to be dropped is based on its conclusion that there was no foundation for the claim when the suit was filed. USVO, though, offers the equally plausible argument that it simply came to believe that pursuing these claims had become economically unviable. Since Movielink has failed to show that USVO lacked a basis to assert infringement by the Big-Foot system, USVO's decision to drop those claims after learning that the system was no longer in use does not imply bad faith.

*5 Therefore, I conclude that Movielink has failed to show that USVO's infringement case against the Big-Foot system was baseless, and an award under § 285 is not appropriate.

2. *Section 1927*

Movielink also contends that USVO's attorneys unreasonably multiplied proceedings in this case by asserting its patent against the Big-Foot system. However, for the same reasons that Movielink's § 285 claim fails, an award under § 1927 is not justified. [FN6]

FN6. USVO's argument that § 1927 applies only to individual attorneys and not to law firms conflicts with Third Circuit precedent, and so I address the merits of Movielink's assertions. *See Baker Indus.*, 764 F.2d at 206-12 (affirming an award under § 1927 against a law firm).

B. *Doctrine of Equivalents*

1. *Section 285*

Movielink argues that USVO pursued infringement claims under the doctrine of equivalents without adequate pre-filing investigation. The argument is based on USVO's failure to respond to Movielink's prosecution history estoppel arguments on summary judgment, a USVO attorney's comments about the difficulties faced by USVO, and the lack of analysis of the doctrine of equivalents by USVO's infringement expert. However, these assertions do not show that USVO pursued a baseless claim.

First, Movielink asserts that USVO "ignored the narrowing amendments made during prosecution of the '792 patent" that ultimately led to USVO being estopped from asserting infringement under the doctrine of equivalents. (D.I. 175 at 25.) *See USA Video*, 354 F.Supp.2d at 522. However, while USVO

argued unsuccessfully that the parties could not adequately address the doctrine of equivalents until after the court issued a claim construction, there is no indication that it ignored the prosecution history that turned out to be dispositive. The fact that an argument fails does not make it baseless.

Second, the attorney comments to a reporter about the '792 patent were made more than six months before the complaint against Movielink was filed on April 10, 2003. (D.I. 187 at ¶ 4.) His views on the difficulty faced by USVO in asserting infringement under the doctrine of equivalents do not establish Movielink's conclusion that such a claim would be baseless.

Third, the absence of an analysis of infringement under the doctrine of equivalents in the September 25, 2004 expert report is consistent with USVO's argument, albeit an unsuccessful one, that the issue should be dealt with after the claims were construed. Again, while not successful, this argument fails to show that USVO pursued a baseless infringement theory.

Therefore, I conclude that Movielink has failed to demonstrate that USVO's infringement case under the doctrine of equivalents was baseless, and an award under § 285 is not appropriate.

2. *Section 1927*

Based on the same factual allegations, Movielink contends that USVO's attorneys unreasonably multiplied proceedings in this case by asserting infringement under the doctrine of equivalents. Once more, the failure of proof as to the § 285 claim means that an award under § 1927 is also not justified.

V. CONCLUSION

Accordingly, it is hereby ORDERED that the Motion for Partial Attorneys' Fees and Costs is DENIED.

D.Del.,2005.
USA Video Technology Corp. v. Movielink, LLC
Slip Copy, 2005 WL 3418407 (D.Del.)

END OF DOCUMENT

EXHIBIT 5

Westlaw.

Not Reported in F.Supp.
Not Reported in F.Supp., 1992 WL 330263 (N.D.Cal.), 1992-2 Trade Cases P 69,993
(Cite as: Not Reported in F.Supp.)

Briefs and Other Related Documents

United States District Court, N.D. California.
CALIFORNIA ENERGY CO., INC.
v.
SOUTHERN CALIFORNIA EDISON, CO., et al.
No. C 91-0319-JPV.

Sept. 22, 1992.

Order Denying Kidder Defendants' Motion for Partial Summary Judgment

Introduction

VUKASIN, District Judge.
*1 The Kidder Defendant's Motion for Summary Judgment was scheduled to be heard on September 10, 1992. After a review of the briefs, this Court submitted the motion without oral argument pursuant to Local Rule 220-1, and now Denies the motion.

Background

Plaintiff, California Energy Company, Inc. ("California Energy"), is an independent power producer which, pursuant to California Public Utilities Commission ("CPUC") regulations must sell the power it produces to defendant power utility Southern California Edison ("Edison") In its third amended complaint, California Energy alleges that Edison, together with defendant investment bankers Kidder, Peabody & Co. and Kidder employee Short ("Kidder defendants"), conspired to, attempted to, and did unreasonably restrain trade and monopolize various relevant markets for the generation of power for resale within Edison's service area in violation of § § 1 and 2 of the Sherman Act. California Energy also alleges causes of action based on state law for conspiracy to interfere with contractual relations and for tortious interference with prospective economic advantage.

California Energy alleges that the Kidder defendants participated in the antitrust conspiracy by employing "bear raid" tactics, including, among other things:

(1) Repeatedly contacting a CPUC staff person with the intent to influence him to take a position against California Energy in a dispute between California Energy and Edison pending before the CPUC (Complaint ¶ 38(e));

(2) Making phone calls to individuals at investment banking firms that were contemplating a securities offering on behalf of California Energy, attempting to dissuade the firms from making the securities offerings (Complaint ¶ 38(f)).

(3) Publishing an equity report severely critical of California Energy (Complaint § 38(a));

California Energy alleges that the effect of the conspiracy involving Edison and the Kidder defendants was to substantially weaken California Energy's growth and lessen its market share (Complaint ¶ 39).

The Kidder defendants have filed this motion for partial summary judgment on the claims incorporating the above allegations.

The Standard for Summary Judgment

Summary judgment should be granted where it is shown that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. *See* Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548 (1986); *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 106 S.Ct. 2505 (1986). In *Celotex*, the Supreme Court made it clear that summary judgment. when appropriate, is a favored method of resolution, and that:
summary judgment is mandated, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will bear the burden of proof at trial

*2 *Celotex*, 477 U.S. at 322, 106 S.Ct. at 2552.

In addition, the Court emphasized in *Anderson* that. under Fed.R.Civ.P. 56(e), "when a properly supported motion for summary judgment is made, the adverse party 'must set forth specific facts showing

that there is a genuine issue for trial.' " *Anderson*, 477 U.S. at 250, 106 S.Ct. at 2511.

Discussion

I. *Kidder's Contacts with the CPUC*

The Kidder defendants move for partial summary judgment on the causes of action incorporating allegations regarding Kidder's contacts with the CPUC, alleging that California Energy's claims regarding these contacts are defective for four separate reasons: no evidence of causation, improper collateral attack on a final judgment, the privilege of statements made in a judicial proceeding shields these contacts, and the first amendment immunizes these contacts.

A. Causation

The Kidder defendants argue that they are entitled to summary judgment on all claims based upon its contacts with the CPUC because California Energy has not presented evidence that Kidder's contacts with the CPUC staff member was an actual cause of the CPUC's decision in the dispute between California Energy and Edison. In support of this proposition, Kidder points to the text of the CPUC decision which Kidder contends makes no mention of California Energy's financial condition. [EN1]

Even if the Kidder defendants' evidence did compel a finding that Kidder's contacts with the CPUC did not influence the CPUC's decision-which was adverse to California Energy-this Court would not be compelled to grant defendants' motion for summary judgment. California Energy's claims against Kidder are based on antitrust theories of conspiracy and attempt to monopolize. In antitrust conspiracy cases, the Ninth Circuit has held that the plaintiff need not prove that each of the alleged overt acts in furtherance of the conspiracy is a separate, direct cause of harm to it. *Ostrofe v. H.S. Crocker Co., Inc.* [1984-2 TRADE CASES ¶ 66,148], 740 F.2d 739, 743 (9th Cir.1984). The plaintiff need only prove that it suffered causal antitrust injury resulting from the defendants' entire course of conduct in violation of the antitrust laws. [P]laintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each. " * * * [T]he character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole."

Ostrofe at 743 (quoting *Continental Ore Co. v. Union Carbine & Carbon Corp.* [1962 TRADE CASES ¶ 70,361], 370 U.S. 690, 699 (1962))

Accordingly, here, where California Energy alleges attempted monopolization, conspiracy to monopolize and monopolization, as well as a conspiracy in restraint of trade, California Energy's allegations should not be dissected as individual acts, as the Kidder defendants assert, but rather must be viewed as a whole. California Energy therefore need not allege or prove causation and damages flowing from each act committed in furtherance of this unlawful intent and scheme. Thus, even if the Kidder defendants had proved that the CPUC decision was not in any way caused by Kidder's contacts with the CPUC staff member, summary judgment would not be compelled, provided that a genuine issue of material fact remains regarding California Energy's claims that Kidder's anticompetitive conduct taken as a whole caused injury to California Energy. While it may be argued that Kidder has met its *Celotex* burden with regard to the discrete subject of its contacts with the CPUC, it is clear that Kidder has not met that burden with regard to its phone calls to investment bankers and its issuance of a disparaging equity report. [EN2] Thus, California Energy's claims are not subject to summary judgment because a triable issue of fact remains regarding injury to California Energy caused by the Kidder defendants' conduct.

B. Collateral Attack on Final Judgment

***3** The Kidder defendants contend that California Energy's claims constitute an impermissible collateral attack on the final judgment rendered against California Energy by the CPUC. This contention is without merit. California Energy is not seeking to prevent enforcement of the CPUC's decision or to defeat any rights acquired under it; California Energy simply alleges that Kidder's contacts with the CPUC are part of an overall illegal intent and scheme to damage California Energy's market position.

C. California Civil Code § 47(b) Privilege

The Kidder defendants' contacts with the CPUC are not privileged under California Civil Code § 47(b), which, in relevant part, privileges communications made during the course of judicial or quasi-judicial

proceedings. Assuming that Kidder's contacts with the CPUC were made during the course of the CPUC hearing, [FN3] § 47(b) still is not applicable to Kidder's conduct. This section operates not as an evidentiary privilege, but rather a limitation on liability.

[W]hile section 47[b] bars certain tort causes of action which are predicated on a judicial statement or publication itself, the section does not create an evidentiary privilege for such statements. Accordingly, when allegations of misconduct properly put an individual's intent at issue in a civil action, statements made during the course of a judicial proceeding may be used for evidentiary purposes in determining whether the individual acted with the requisite intent

Oren Royal Oaks Venture v. Greenberg, Bernhard, Weiss & Karma, 42 Cal.3d 1159, 1168 (1986).

Here, California Energy does not allege a cause of action "predicated on a judicial statement or publication itself," but rather seeks to use the fact that Kidder intentionally and wrongfully interfered with the CPUC decision as evidence of Kidder's anticompetitive scheme. Accordingly, § 47(b) does not operate to bar use of Kidder's contacts with the CPUC as evidence of an underlying course of wrongful anticompetitive conduct.

D. The First Amendment

Kidder argues that its contacts with the CPUC are shielded by the first amendment's rights of association and petition. A similar argument was rejected by the Ninth Circuit in *Clipper Exxpress v. Rocky Mountain Motor Tariff* [1982-83 TRADE CASES ¶ 65,063], 690 F.2d 1240 (9th Cir.1982). There, the court held that defendants' legal protests before the Interstate Commerce Commission could be used to establish elements of an antitrust conspiracy claim when the petitioning activity was but a part of a larger overall scheme to restrain trade. *Id.* at 1263. Similarly here, California Energy is not merely challenging Kidder's petitioning activity before the CPUC; rather, it is also challenging Kidder's entire course of conduct. Accordingly, the first amendment does not immunize Kidder from liability for violations of the antitrust laws.

II. Kidder's Calls to Investment Banking Firms

The Kidder defendants assert that they are entitled to partial summary judgment on the causes of action incorporating allegations of Kidder's contacts with investment banking firms for three separate reasons: no evidence of causation, privilege of opinion, and privilege of communication between interested parties

A. Causation

***4** California Energy alleges that the Kidder defendants made phone calls to two investment banking firms that California Energy had employed to raise capital through a securities offering, imparting damaging-and allegedly misleading-information regarding California Energy. Kidder argues that the phone calls did not have any causal effect upon the firms' decisions not to proceed with the securities offerings, and thus cannot be the basis for liability.

Here again, as with the allegations regarding the CPUC contacts, Kidder is not entitled to summary judgment because-even if the phone calls did not influence the banking firms' decisions-these calls are but evidence of a larger alleged anticompetitive scheme. Again, California Energy need not prove that each of the alleged overt acts in furtherance of the conspiracy was a separate, direct cause of harm to it; it need only prove that it suffered causal antitrust injury resulting from the defendant's entire course of conduct. *Ostrofe v. H.S. Crocker Co., Inc.*, 740 F.2d 739, 743 (9th Cir.1984). Thus, the allegations regarding Kidder's phone calls to the other investment banking firms are not subject to summary judgment for a lack of evidence proving that these calls caused California Energy direct harm.

B. Privilege for Statements of Opinion

Kidder contends that these phone calls only expressed opinions, and thus are not properly the basis for liability. Kidder's argument would be meritorious if this were a defamation action; however, this is an antitrust action in which the distinction between fact and opinion is irrelevant. Statements of opinion constituting anticompetitive conduct may be the basis for antitrust liability just as may statements of fact.

C. California Civil Code § 47(c) Privilege

Kidder also argues that these phone calls are privileged under California Civil Code § 47(c).

which provides in relevant part that "[a] privileged publication ... is one made [i]n a communication, without malice, to a person interested therein, (1) by one who is also interested...." "Interested persons" within the meaning of this section have been defined as "a communicator and a recipient with a common interest." *Cuenca v. Safeway San Francisco Employees Federal Credit Union*, 180 Cal.App.3d 985, 996 (1986). Such a common interest is limited to special relationships such as the relationship in a commercial setting between a past and prospective employer of an employee regarding the conduct of that employee. No such special relationship exists here between Kidder and the investment banking firms contacted by Kidder regarding the prospective securities offering. Contrary to Kidder's arguments, the fact that Kidder and these firms are engaged in the same line of business is not sufficient to establish the privilege; neither is the possibility that Kidder and the other firms were both interested in the affairs of California Energy. Accordingly, the § 47(c) privilege is not available.

III. Kidder's Issuance of Equity Report

A. Statute of Limitations

***5** Kidder relies on California's Uniform Single Publication Act (California Civil Code § 3425) in contending that any claims based upon the issuing of the equity report are time barred because California Energy's claims were brought more than one year after the publication of the report. This reliance is misplaced.

First, as to the antitrust claims (causes of action one and two), the state rule does not apply because federal law governs the accrual and length of the statute of limitations for those claims.

The third and fourth causes of action (conspiracy to interfere with contractual relations and tortious interference with prospective economic advantage) are based on state law. Kidder contends that the Single Publication Act should apply to these claims, which provides that "[n]o person shall have more than one cause of action for damages for libel or slander or invasion of privacy or any other tort founded upon any single publication or exhibition or utterance...."

The Single Publication Act does not, however, establish a statute of limitations. It does establish the time for a cause of action accruing-the date of the earliest publication of the material. The statute of limitations for the particular cause of action is set by the applicable code section. Here, the third and fourth causes of action are prescribed a two year statute of limitations by California Civil Procedure Code § 339(1). The causes accrued under the Single Publication Act on the date the equity report was first distributed, February 24, 1989. This case was filed on January 31, 1991, within the two year statutory period. Thus, the third and fourth causes of action are not time barred.

Order

In accordance with the foregoing discussion, defendants' motion for partial summary judgment on causes of action incorporating allegations regarding:

(1) Defendants' contacts with the CPUC,

(2) Defendants' contacts with investment banking firms, and

(3) Defendants' issuing of an equity report, is hereby Denied.

It Is So Ordered.

FN1. Kidder also alleges that the CPUC "staff member" contacted by the Kidder employee was not a member of the CPUC department which was deciding the dispute between California Energy and Edison. This information comes in the form of inadmissible hearsay, and therefore cannot be considered in ruling on defendant's motion.

FN2. With regard to the phone calls to investment bankers, discussed *infra* at II. the depositions of the contacted bankers give rise to a dispute as to whether the calls from Kidder influenced the bankers to abandon plans for a public securities offering on behalf of California Energy or change their business position towards California Energy. (See California Energy's Statement of Disputed Facts ¶ ¶ 20-23, 31-33). Moreover, California Energy's allegations that Kidder's issuance of the equity report, discussed *infra* at III, caused investors to immediately sell California Energy's stock

> and cause the price of its stock to plummet are not disputed by Kidder. Because Kidder has not met its *Celotex* burden regarding the issuance of the equity report, California Energy's antitrust claims can withstand the motion for summary judgment for lack of evidence of causation on this basis alone.
>
> FN3. An assumption that does not appear compelled by the pleadings, given that Kidder's comments regarding California Energy were not made at the hearings and were not solicited by the CPUC.

N.D.Cal.,1992.
California Energy Co., Inc. v. Southern California Edison Co.
Not Reported in F.Supp., 1992 WL 330263 (N.D.Cal.), 1992-2 Trade Cases P 69,993

Briefs and Other Related Documents (Back to top)

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